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Functional Neuroimaging Information: A Case For Neuro Exceptionalism

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FUNCTIONAL NEUROIMAGING INFORMATION: A CASE FOR NEURO EXCEPTIONALISM

Stacey A. Torvino

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FUNCTIONAL NEUROIMAGING INFORMATION: A CASE FOR NEURO EXCEPTIONALISM?

STACEY A. TOVINO, J.D., PH.D.*

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I. INTRODUCTION

The field of neuroethics has been described as an amalgamation of two branches of inquiry: “the neuroscience of ethics” and “the ethics of neuroscience.”¹ The neuroscience of ethics may be described as “a scientific approach to understanding ethical behavior.”² The law and ethics of neuroscience is concerned with the legal and ethical principles that should guide brain research and the treatment of neurologi-

* Assistant Professor of Law, Hamline University School of Law. I am grateful to Bill Winslade, Cheryl Ellis Vaiani, Judy Illes, Ron Carson, and Melvyn Schreiber for their comments on earlier versions of this Article; Maité Morales-Martínez for her outstanding research assistance; and Regina Watson and Barb Kallusky in the Hamline Law Library for their assistance with locating difficult sources.

1. Adina Roskies, *A Case Study of Neuroethics: The Nature of Moral Judgment*, in *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* 17, 18 (Judy Illes ed., 2006).

2. *Id.*

cal disease, as well as the effects that advances in neuroscience have on our social, moral, and philosophical views.³ This Article is a contribution to the law and ethics of neuroscience.

No longer new⁴ or emerging, the burgeoning⁵ field of neuroethics has an expanding literature that includes several edited collections,⁶ journal symposia,⁷ and stand-alone texts.⁸ Based on topics as varied as neurodegenerative disease, functional neuroimaging, incidental neuroimaging findings, transcranial magnetic stimulation, functional neurosurgical interventions, and cognitive enhancement, neuroethics has developed alongside its neuroeconomics⁹ and neuropolitics¹⁰ counterparts and is followed by triple-disciplinary fields such as law and neuroeconomics.¹¹ In this Article, I focus on one small part of the field of neuroethics: the confidentiality, privacy, and identity implications of advances in functional magnetic resonance imaging (fMRI).

Now in its second decade, fMRI identifies localized changes in blood oxygenation that occur in the brain when an individual per-

3. *See id.*

4. Arthur L. Caplan, *Foreword* to *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* vii, vii (Judy Illes ed., 2006).

5. Jeff Stryker, *How Brainwashing Came to Life and Thrived*, *SAN FRAN. CHRON.*, Aug. 1, 2004, at E1.

6. *See, e.g.*, SEMIR ZEKI & OLIVER GOODENOUGH, *LAW AND THE BRAIN* (2006); *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* (Judy Illes ed., 2006); *NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE* (Brent Garland ed., 2004); *NEUROETHICS: MAPPING THE FIELD* (Steven J. Marcus ed., 2002); Walter Glannon, *Defining Right and Wrong in Brain Science: Essential Recordings in Neuroethics* (2007).

7. *See, e.g.*, Symposium, *Brain Imaging and the Law*, 33 *AM. J.L. & MED.* (forthcoming 2007); Symposium, *What Can Neuroscience Contribute to Ethics?*, 32 *J. MED. ETHICS* 63 (2006); Symposium, *It's Time to Go Public with Neuroethics*, *AM. J. BIOETHICS*, Mar.-Apr. 2005, at I-63; Symposium, *Neuroethics: An Emerging New Discipline in the Study of Brain and Cognition*, 50 *BRAIN & COGNITION* 341 (2002).

8. *See, e.g.*, SANDRA J. ACKERMAN, *HARD SCIENCE, HARD CHOICES: FACTS, ETHICS, AND POLICIES GUIDING BRAIN SCIENCE TODAY* (2006); MICHAEL S. GAZZANIGA, *THE ETHICAL BRAIN* (2005); NEIL LEVY, *NEUROETHICS: CHALLENGES FOR THE 21ST CENTURY* (2007); STEVEN ROSE, *THE FUTURE OF THE BRAIN: THE PROMISE AND PERILS OF TOMORROW'S NEUROSCIENCE* (2005); LAURENCE R. TANCREDI, *HARDWIRED BEHAVIOR: WHAT NEUROSCIENCE REVEALS ABOUT MORALITY* (2005); *THE NEW BRAIN SCIENCES: PERILS AND PROSPECTS* (Dai Rees & Steven Rose, eds., 2004).

9. *See generally* Colin Camerer et al., *Neuroeconomics: How Neuroscience Can Inform Economics*, 43 *J. ECON. LITERATURE* 9 (2005); Colin F. Camerer et al., *Neuroeconomics: Why Economics Needs Brains*, 106 *SCANDINAVIAN J. ECON.* 555 (2004); Colin F. Camerer, *Strategizing in the Brain*, 300 *SCI.* 1673 (2003); Kevin McCabe et al., *Neuroeconomics*, in *ENCYCLOPEDIA OF COGNITIVE SCIENCE* 294 (Lynn Nadel ed., 2003); Kevin McCabe et al., *A Functional Imaging Study of Cooperation in Two-Person Reciprocal Exchange*, 98 *PROC. NAT'L ACAD. SCI.* 11832 (2001).

10. *See generally* WILLIAM E. CONNOLLY, *NEUROPOLITICS: THINKING, CULTURE, SPEED* (Sandra Buckley et al. eds., *THEORY OUT OF BOUNDS* No. 23, 2002).

11. *See generally* Terrence Chorvat et al., *Law and Neuroeconomics*, 13 *SUP. CT. ECON. REV.* 35 (2005).

forms a mental task.¹² Scientists use fMRI not only to map sensory, motor, and cognitive function but also to study the neural correlates of a number of conditions, behaviors, and characteristics, such as major depression, schizophrenia, cocaine addiction, compulsive gambling, pedophilia, racial evaluation, deception, and even sexual preferences.¹³ Now moving outside the research context, fMRI's ability to detect correlations between brain activations and potentially stigmatizing conditions and behaviors raises a number of confidentiality, privacy, and identity issues.

The neuroethics literature has been calling for an in-depth analysis of these issues. *Science* editor Donald Kennedy suggested in 2002 that fMRI could jeopardize confidentiality and privacy.¹⁴ Judy Illes, Director of the Program in Neuroethics at the Stanford Center for Biomedical Ethics, requested legal consideration of the need for additional confidentiality and privacy protections for thought processes in 2003.¹⁵ University of Pennsylvania psychologist Martha Farah expressed similar concerns in 2004.¹⁶ Harvard criminal law scholar William Stuntz pondered in 2005 the pressure that fMRI could place on the judicial system's understanding of privacy.¹⁷ The same year, José van Dijck, Professor of Media and Culture at the University of Amsterdam, inquired more generally regarding how the camera pushes the limits of privacy.¹⁸ More recently, a 2007 *New York Times* article asked how brain scanning technologies will threaten our privacy.¹⁹

This Article responds to these questions and concerns. Elsewhere, I placed the confidentiality, privacy, and identity issues raised by fMRI in their proper historical context.²⁰ Here, I build on my earlier

12. David G. Norris, *Principles of Magnetic Resonance Assessment of Brain Function*, 23 J. MAGNETIC RESONANCE IMAGING 794-95 (2006).

13. See *infra* text accompanying notes 198-226.

14. *The Ethics of Brain Science: Open Your Mind*, ECONOMIST, May 25, 2002, available at 2002 WLNR 10444593 ("Medical privacy is another area that brain scanning could compromise.").

15. Judy Illes, *Neuroethics in a New Era of Neuroimaging*, 24 AM. J. NEURORADIOLOGY 1739, 1740 (2003) ("Just as the regulations of the new . . . Health Insurance Portability and Accountability Act extend The Belmont Report principles and guidelines for the protection of human participants in research, what will protect the quantitation of human thought in 2010?").

16. Martha J. Farah & Paul Root Wolpe, *Monitoring and Manipulating Brain Function: New Neuroscience Technologies and Their Ethical Implications*, HASTINGS CENTER REP., May-June 2004, at 35, 36 ("Our sense of the privacy and confidentiality of our own thought processes may also be threatened by technologies that can reveal the neural correlates of our innermost thoughts.").

17. Jeffrey Rosen, *Roberts v. The Future*, N.Y. TIMES, Aug. 28, 2005, § 6, at 24.

18. JOSÉ VAN DIJCK, *THE TRANSPARENT BODY: A CULTURAL ANALYSIS OF MEDICAL IMAGING* 13 (2005).

19. Jeffrey Rosen, *The Brain on the Stand: How Neuroscience Is Transforming the Legal System*, N.Y. TIMES MAG., Mar. 11, 2007, at 48, 50.

20. Phrenology, the nineteenth-century pseudoscience of the mind, was believed to be capable of revealing character information that individuals may have preferred to keep

work by examining the current confidentiality, privacy, and identity issues raised by fMRI. I specifically examine whether existing legal and ethical principles give individuals sufficient control over the use and disclosure of their functional neuroimaging information by third parties (confidentiality), the collection of their functional neuroimaging information by third parties (privacy), and the self-revelation of their functional neuroimaging information (identity).

This Article proceeds as follows. Part II provides an abbreviated history of fMRI. Part III explores the actual and perceived scope of confidentiality, privacy, and identity concerns raised by advances in functional neuroimaging. What brain functions does fMRI actually reveal? What can fMRI tell us about an individual's physical or mental health condition or her social qualities and personal characteristics? Can fMRI reveal whether an individual is racially prejudiced, deceitful, or altruistic? Whether an individual is depressed, sexually aroused, or capable of making moral decisions? To answer these questions, Part III reviews a selection of fMRI studies and explains why private and governmental entities are interested in obtaining and creating neuroimaging information and how the media, with some help from bioethicists and other stakeholders, may be contributing to this interest.

An oft-stated principle is that physicians and scientists have a legal and an ethical duty to maintain the confidentiality of study and medical records in their possession.²¹ Do existing authorities adequately protect an individual's interest in the appropriate use and disclosure of her functional neuroimaging information? To answer this question, Part IV examines a selection of legal authorities, including the Common Rule, the Privacy Rule, state confidentiality laws, and Public Health Service provisions providing for certificates of confidentiality.

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 third party attempts to collect neuroimaging information that an individual would prefer to keep to herself? Part V responds to this concern by analyzing the privacy issues raised by

private. The discovery of x-ray at the turn of the century led to the development of a number of privacy protections, including lead underwear and legislation prohibiting the use of x-ray glasses. The ability of computed tomography and structural magnetic resonance imaging to peer inside the body intensified privacy concerns, especially as the forensic value of these technologies became known. Old and new methods of brain mapping and neuroimaging raise confidentiality, privacy, and identity concerns, and history has a role in informing current policy discussions about fMRI. *See generally* Stacey A. Tovino, *Imaging Body Structure and Mapping Brain Function: A Historical Approach*, 33 AM. J.L. & MED. (forthcoming 2007).

21. *See infra* Part IV.

fMRI. Part V is structured according to a selection of contexts in which neurological privacy intrusions could occur, including the clinical, research, employment, and insurance contexts.

Part VI explores the identity issues raised by fMRI. In several recent studies, scientists have incidentally discovered arteriovenous malformations, brain tumors, developmental abnormalities, and other conditions in what were thought to be healthy control subjects who volunteered to participate in fMRI research. The possibility that scientists and other brain scan operators could collaterally identify personality traits, sexual preferences, and racial preferences is currently the subject of much debate. Part VI examines whether the law affords individuals adequate control over the self-revelation of their functional neuroimaging information.

Finally, Part VII addresses whether advances in functional neuroimaging require special or heightened confidentiality, privacy, and identity provisions. Building on the frameworks of HIV exceptionalism and genetic exceptionalism, Part VII evaluates the merits of neuro exceptionalism. En route to arguing that advances in neuroimaging technology support previous calls for generic privacy provisions in the employment and insurance contexts, Part VII also addresses the roles and responsibilities of scientists, ethicists, and lawyers in the public and neuroethics arenas.

II. FMRI: A BRIEF HISTORY

Although the science behind magnetic resonance dates back to the 1920s,²² commercial magnetic resonance imaging scanners were not developed until the late 1970s.²³ In 1977, Raymond Damadian and his FONAR Corporation built the first human nuclear magnetic resonance scanner, which used magnetism and radio waves to image internal organs and tissues.²⁴ On July 3 of that year, Larry Minkoff, a postdoctoral fellow in Damadian's laboratory, was the first human subject from whom data was recorded by a nuclear magnetic resonance scanner.²⁵ The resulting image, which showed a slice of Minkoff's chest including his heart, lungs, and surrounding muscles, took almost four hours to complete.²⁶ By 1979, Damadian and other researchers had used nuclear magnetic resonance imaging technology to create images of individuals' abdomens, upper torsos, heads, and brains, the latter of which had been especially difficult to obtain using x-ray.²⁷ Around the same time, the adjective "nuclear" was

22. SCOTT A. HUETTEL ET AL., FUNCTIONAL MAGNETIC RESONANCE IMAGING 11 (2004).

23. *Id.* at 19.

24. *Id.*

25. *Id.* at 20.

26. *Id.*

27. *Id.*

dropped from the technology due to the negative health connotations of the word and the fact that nuclear magnetic resonance does not use ionizing radiation.²⁸ Nuclear magnetic resonance thus became known as magnetic resonance imaging (MRI).²⁹

By the early 1980s, several companies had developed industrial MRI scanners with magnetic fields of 0.1 to 1.0 Tesla.³⁰ In 1982, General Electric created a commercial, human-body scanner with a relatively strong (1.5-Tesla) magnetic field in 1982.³¹ A short time later, hospitals began installing the scanners, which became the standard scanner for clinical imaging for the next twenty years.³² In 1985, the Food and Drug Administration approved MRI for clinical use, which allowed health care providers to order MRI scans and bill them to health insurance companies.³³ By the mid-1990s, thousands of MRI scanners had been installed in hospitals and imaging centers across North America, and structural MRI had become a common diagnostic imaging procedure.³⁴

Although MRI is capable of measuring structural differences between brain tissues, it does not measure brain function, as does functional magnetic resonance imaging (fMRI).³⁵ A brief history of the physiological basis of fMRI is necessary to understand the fMRI studies discussed in Part III. In 1881, Italian physiologist Angelo Mosso recorded the pulsation of the human cortex in post-neurosurgery patients with skull defects.³⁶ Mosso found that the “pulsations increased regionally during mental activity” and concluded that “brain circulation changes . . . with neuronal activity.”³⁷ In 1936, American chemist and Nobel Prize winner Linus Pauling and one of his students, Charles Coryell, discovered that deoxygenated blood has approximately one-fifth more magnetic susceptibility than fully oxygenated blood.³⁸ Pauling and Coryell predicted that magnetic resonance pulse sequences would show different magnetic resonance signals depending on whether blood is highly oxygenated or highly deoxygenated.³⁹ This prediction, which was verified in the early 1980s

28. *Id.*

29. *Id.* at 21.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 24.

36. Marcus E. Raichle, *Functional Neuroimaging: A Historical and Physiological Perspective*, in *HANDBOOK OF FUNCTIONAL NEUROIMAGING OF COGNITION* 3, 5 (Roberto Cabeza & Alan Kingstone eds., 2001).

37. *Id.*

38. HUETTELE ET AL., *supra* note 22, at 159-60.

39. *Id.*

by Keith Thulborn and his colleagues, provided a theoretical basis for measuring blood oxygenation changes using MRI.⁴⁰

The possibility of using MRI to study brain physiology was first explored by Seiji Ogawa, a Bell Laboratories research scientist, in the late 1980s.⁴¹ Ogawa hypothesized that blood flow could serve as an indirect measure of metabolism that could be captured by MRI.⁴² More specifically, Ogawa's theory was that changes in blood flow would be accompanied by changes in oxygen consumption, which would lead to measurable changes in the amount of oxygen remaining in blood vessels at the site of brain activation.⁴³

Ogawa tested his hypothesis by using an MRI scanner with a very strong (7-Tesla) magnetic field to image the brains of anesthetized rats while they breathed air with different amounts of oxygen.⁴⁴ Ogawa found that the presence of deoxygenated hemoglobin in blood vessels caused magnetic susceptibility effects that could be imaged.⁴⁵ He verified his findings, which were referred to as blood-oxygenation-level dependent (BOLD) contrast,⁴⁶ in a second experiment in which an MRI scanner was used to image tubes filled with oxygenated and deoxygenated blood. The second experiment confirmed Ogawa's earlier conclusion that the presence of deoxygenated blood changes the magnetic resonance signal relative to the presence of oxygenated blood.⁴⁷ Attempting to verify in a third experiment that BOLD contrast resulted from the metabolic demand for oxygen, Ogawa changed the gases inhaled by anesthetized rats while measuring BOLD contrast at a high magnetic field.⁴⁸ This experiment confirmed that BOLD contrast depends on the metabolic demand for oxygen.⁴⁹

Although Ogawa found in his three initial experiments that MRI could be used to measure changes in blood oxygenation, scientists still needed to demonstrate that MRI could be used to identify the parts of the human brain that were responsible for different func-

40. Keith R. Thulborn et al., *Oxygenation Dependence of the Transverse Relaxation Time of Water Protons in Whole Blood at High Field*, 714 *BIOCHIMICA ET BIOPHYSICA ACTA* 265, 265 (1982).

41. Peter Jezzard & Richard B. Buxton, *The Clinical Potential of Functional Magnetic Resonance Imaging*, 23 *J. MAGNETIC RESONANCE IMAGING* 787, 788 (2006).

42. HUETTELE ET AL., *supra* note 22, at 160.

43. Raichle, *supra* note 36, at 3.

44. HUETTELE ET AL., *supra* note 22, at 160-61.

45. Seiji Ogawa et al., *Oxygenation-Sensitive Contrast in Magnetic Resonance Image of Rodent Brain at High Magnetic Fields*, 14 *MAGNETIC RESONANCE MED.* 68, 68 (1990).

46. See, e.g., Nikos K. Logothetis, *The Underpinnings of the BOLD Functional Magnetic Resonance Imaging Signal*, 23 *J. NEUROSCIENCE* 3963, 3963 (2003)

47. Seiji Ogawa & Tso-Ming Lee, *Magnetic Resonance Imaging of Blood Vessels at High Fields: In Vivo and in Vitro Measurements and Image Simulation*, 16 *MAGNETIC RESONANCE MED.* 9, 9 (1990).

48. S. Ogawa et al., *Brain Magnetic Resonance Imaging with Contrast Dependent on Blood Oxygenation*, 87 *PROC. NAT'L ACAD. SCI.* 9868, 9868 (1990).

49. *Id.*

tions.⁵⁰ Three groups of scientists published BOLD fMRI studies involving human subjects in 1992. In the first study, Kenneth Kwong used a 1.5-Tesla magnetic field to scan the brains of individuals as they alternated between watching a flashing pattern and watching nothing. Kwong found significant activity in the subjects' visual cortex that lasted while the pattern flashed, but receded when nothing was shown.⁵¹ In the second study, Ogawa replicated the findings of Kwong using a higher (4-Tesla) magnetic field.⁵² In a third study, Peter Bandettini scanned the brains of research subjects using a 1.5-Tesla magnetic field while the subjects repeatedly touched their fingers to their thumbs.⁵³ Bandettini found significant activity in the subjects' primary motor cortex.⁵⁴ Although the identification of the parts of the brain responsible for visual and sensorimotor functions had been known since the end of the nineteenth century, the studies of Kwong, Ogawa, and Bandettini replicated earlier findings, thus paving the way for fMRI to be used to study other brain functions.

Today, fMRI is considered a powerful method of imaging human brain function.⁵⁵ In a typical fMRI experiment, subjects are assigned one or more control and experimental tasks, and their brains are scanned during the performance of such tasks.⁵⁶ Functional MRI captures in images the different BOLD contrasts that result from the control and experimental tasks.⁵⁷ By subtracting the control images from the experimental images, maps of the brain showing the areas to which a surplus of oxygenated blood flowed in response to the performance of the experimental tasks can be created.⁵⁸

50. HUETTEL ET AL., *supra* note 22, at 171.

51. Kenneth K. Kwong et al., *Dynamic Magnetic Resonance Imaging of Human Brain Activity During Primary Sensory Stimulation*, 89 PROC. NAT'L ACAD. SCI. 5675, 5675 (1992).

52. Seiji Ogawa et al., *Intrinsic Signal Changes Accompanying Sensory Stimulation: Functional Brain Mapping with Magnetic Resonance Imaging*, 89 PROC. NAT'L ACAD. SCI. 5951, 5951 (1992).

53. Peter A. Bandettini et al., *Time Course EPI of Human Brain Function During Task Activation*, 25 MAGNETIC RESONANCE MED. 390, 391 (1992).

54. *Id.* at 392.

55. See, e.g., Judy Illes et al., *Ethical and Practical Considerations in Managing Incidental Findings in Functional Magnetic Resonance Imaging*, 3 BRAIN & COGNITION 358, 358 (2002); Judy Illes, *Ethical Issues at the Intersection of Imaging and Genomics*, presentation at the Princeton University Symposium: Politics of Biomedical Research: Issues, Information and Policy Decision-Making (Mar. 28, 2003).

56. Judy Illes & Eric Racine, *Imaging or Imagining? A Neuroethics Challenge Informed by Genetics*, AM. J. BIOETHICS, Mar.-Apr. 2005, at 5, 7.

57. See *id.*

58. *Id.*; Jeffrey R. Binder & Stephen M. Rao, *Human Brain Mapping with Functional Magnetic Resonance Imaging*, in LOCALIZATION AND NEUROIMAGING IN NEUROPSYCHOLOGY 185, 193 (Andrew Kertesz ed., 1994); Donald Kennedy, *Neuroimaging: Revolutionary Research Tool or a Post-Modern Phrenology?* AM. J. BIOETHICS, Mar.-Apr. 2005, at 19, 19.

III. fMRI APPLICATIONS

A. Clinical Applications

Functional MRI has a number of current and potential clinical, scientific, and social applications.⁵⁹ Preneurosurgical brain mapping, an early application,⁶⁰ was made possible by scientists who evaluated batteries of pre-operative fMRI tasks in order to identify the areas of the brain that are associated with tactile, motor, language, and visual functions.⁶¹ The brain maps produced by fMRI have helped neurosurgeons assess surgical risk, plan surgical routes, and direct intraoperative electrophysiological procedures.⁶² As one among many possible examples, a research team based out of Washington University in St. Louis used fMRI in 2003 to help them pinpoint the unusual location of language centers in a patient with a long history of severe epileptic seizures.⁶³ Knowledge of the precise location of the language centers was critical to the patient's successful surgical outcome.⁶⁴

Scientists continue to study how fMRI can be used to improve neurosurgery⁶⁵ as well as deep brain stimulation for treatment of Parkinson's disease⁶⁶ and depression.⁶⁷ Medical center press releases not infrequently advertise the ways in which fMRI can help to map functional areas of the brain and preserve brain function.⁶⁸ News reporters also have recognized fMRI's clinical potential, although they seem to be one step ahead of the scientists: "At this rate, it seems that neuroscientists will soon pinpoint the regions in the brain where

59. See generally Symposium, *Clinical Potential of Brain Mapping Using MRI*, 23 J. MAGNETIC RESONANCE IMAGING 785 (2006).

60. See Jeppard & Buxton, *supra* note 41, at 790.

61. Joy Hirsch et al., *An Integrated Functional Magnetic Resonance Imaging Procedure for Preoperative Mapping of Cortical Areas Associated with Tactile, Motor, Language, and Visual Functions*, 47 NEUROSURGERY 711, 711 (2000).

62. *Id.* at 711, 718-20.

63. M.V. Baciú et al., *Functional MRI Reveals an Interhemispheric Dissociation of Frontal and Temporal Language Regions in a Patient with Focal Epilepsy*, 4 EPILEPSY & BEHAV. 776, 776 (2003).

64. *Id.* at 777-79.

65. Paul E. Kim & Manbir Singh, *Functional Magnetic Resonance Imaging for Brain Mapping in Neurosurgery*, 15 NEUROSURGICAL FOCUS 1, 1 (2003).

66. Andres Lozano, *Deep Brain Stimulation: Challenges to Integrating Stimulation Technology with Human Neurobiology, Neuroplasticity, and Neural Repair*, 38 J. REHABILITATION RES. & DEV. x, xi, xvii (2001).

67. David Dobbs, *A Depression Switch?*, N.Y. TIMES, Apr. 2, 2006, § 6, at 50.

68. Gerry Everding, *Better Brain Imaging Helps Surgeons Avoid Damage to Language Functions*, WASHINGTON U. ST. LOUIS NEWS & INFO., Nov. 4, 2003, <http://mednews.wustl.edu/tips/page/normal/494.html> (last visited June 22, 2007); *Functional MRI Used in Brain Activity Mapping for Surgical Planning*, U. IOWA DEPT RADIOLOGY NEWS, June 20, 2001, <http://www.radiology.uiowa.edu/news/mri-surg.html>.

mediocre poetry is generated, where high school grudges are lodged, where sarcasm blooms like a red rose.”⁶⁹

B. Understanding Racial Evaluation

Functional MRI also has a number of study applications. Sociological research over the last several decades has showed that self-reports of prejudicial attitudes towards individuals of other racial groups have declined⁷⁰ and that fewer White Americans express negative attitudes towards Black Americans now than forty years ago.⁷¹ Notwithstanding these findings, scientists continue to observe negative evaluations of individuals of different racial groups in studies that bypass access to conscious awareness and control.⁷² One of the goals of the field of social cognition is to understand the nature of these unconscious evaluations,⁷³ and scientists believe that fMRI may be helpful in this regard.⁷⁴

The response of the amygdala—a small, almond-shaped structure in the medial temporal lobe that is best known for its role in emotional learning and memory—to photographs of individuals of different racial groups was first studied by Allen Hart and his colleagues in 2000.⁷⁵ The scientists used fMRI to acquire images while eight healthy subjects between twenty and thirty-five years of age who had identified themselves as Black or White were presented with sixty grayscale photographs of Black and White faces.⁷⁶ During the later stimulus presentations, the scientists observed significantly greater BOLD signal in the amygdala in response to outgroup (individuals of a different race) versus ingroup (individuals of their own race) faces.⁷⁷ The scientists concluded that amygdala responses to human face stimuli must be affected by the relationship between the perceived race of the stimulus face and that of the subject.⁷⁸ Although their data “provide[d] a foundation for future related studies in the neuroscience of social cognition and race,”⁷⁹ the scientists cautioned

69. Benedict Carey, *Searching for the Person in the Brain*, N.Y. TIMES, Feb. 5, 2006, § 4, at 41.

70. Elizabeth A. Phelps et al., *Performance on Indirect Measures of Race Evaluation Predicts Amygdala Activation*, 12 J. COGNITIVE NEUROSCIENCE 729, 729 (2000).

71. Elizabeth A. Phelps & Laura A. Thomas, *Race, Behavior, and the Brain: The Role of Neuroimaging in Understanding Complex Social Behaviors*, 24 POL. PSYCHOL. 747, 751 (2003).

72. *See id.* at 752.

73. Allen J. Hart et al., *Differential Response in the Human Amygdala to Racial Outgroup vs. Ingroup Face Stimuli*, 11 NEUROREPORT 2351 (2000).

74. *See id.*

75. *Id.* at 2351.

76. *Id.* at 2352.

77. *Id.* at 2352-53.

78. *Id.* at 2353-54.

79. *Id.* at 2351.

against drawing premature conclusions, emphasizing the lack of BOLD signal difference observed during initial (as opposed to later) stimulus presentations.⁸⁰

Elizabeth Phelps and her colleagues conducted a second study in 2000 that “used fMRI to explore the neural substrates involved in the unconscious evaluation of Black and White social groups.”⁸¹ In her first experiment, Phelps used fMRI to acquire images while presenting White American subjects with pictures of unfamiliar Black and White male faces with neutral facial expressions.⁸² Phelps found that “variability in amygdala activation among White subjects is correlated with negative indirect responses to Black compared to White faces on behavioral measures.”⁸³ This finding led Phelps to her now famous conclusion “that representations of social groups that differ in race evoke differential amygdala activity and that such activation is related to unconscious social evaluation.”⁸⁴ Phelps found the activity in the left-superior amygdala significant in light of findings that that region is activated when fearful (versus neutral) facial expressions are presented.⁸⁵

Phelps also had hypothesized that any amygdala activity that was observed during the first experiment would disappear if she showed her subjects “exemplars of Black Americans who are as familiar and well liked as White Americans.”⁸⁶ To test this hypothesis, Phelps conducted a second experiment in which she presented to her subjects pictures of famous and positively regarded Black individuals, including Martin Luther King, Jr., Michael Jordan, and Will Smith.⁸⁷ Phelps observed “no consistent pattern of amygdala activity” in her second experiment.⁸⁸ The results of both experiments suggest that the amygdala may be specifically involved in indirect or unconscious responses to racial groups and that amygdala response “is a function of culturally acquired information about social groups, modified by individual knowledge and experience.”⁸⁹ Phelps concluded by noting that she had, “for the first time, related indirect behavioral measures

80. *Id.* at 2353-54.

81. Phelps et al., *supra* note 70, at 729.

82. *Id.* at 730.

83. *Id.* at 733.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.* at 736.

88. *Id.* at 733.

89. *Id.* at 734.

of social evaluation to neuronal activity.”⁹⁰ Investigators continue to build on the initial work of Hart, Phelps, and their colleagues.⁹¹

Following the publication of Phelps’ research, some speculated that advances in functional neuroimaging technology could be used to reveal individuals’ racial preferences and even prejudices.⁹² Radio and news reports carried headlines such as *Racial Bias on the Brain*,⁹³ *Inside the Mind of a Racist: Scans May Reveal Brain’s Hidden Centres of Prejudice*,⁹⁴ and *Hiding Racial Bias Can Tax Brain*.⁹⁵ Perhaps in response to headlines such as these, Phelps issued a statement expressly warning against using fMRI to detect racism: “The measures used in this research should not and cannot be assumed to be a battery of tests that can be used to reveal an individual’s hidden racism. It would be improper to use them in any selection or diagnostic context.”⁹⁶ Phelps also argued that “we should not label someone ‘racist’ because of the pattern of his or her brain response”⁹⁷ and that brain science should not yet be used to guide social and political choices.⁹⁸

C. Detecting Deception

According to the federal Office of Technology Assessment, polygraph—which relies on skin conductance, heart rate, and respiration—is currently the most widely used method for detection of de-

90. *Id.*

91. See, e.g., William A. Cunningham et al., *Separable Neural Components in the Processing of Black and White Faces*, 15 PSYCHOL. SCI. 806, 806 (2004); Jennifer L. Eberhardt, *Imaging Race*, AM. PSYCHOLOGIST 181 (2005) (reviewing the literature in the neuroscientific study of race); Matthew D. Lieberman et al., *An fMRI Investigation of Race-Related Amygdala Activity in African-American and Caucasian-American Individuals*, 8 NATURE NEUROSCIENCE 720, 720 (2005); Elizabeth A. Phelps et al., *Intact Performance on an Indirect Measure of Race Bias Following Amygdala Damage*, 41 NEUROPSYCHOLOGIA 203, 203 (2003); Mary E. Wheeler & Susan T. Fiske, *Controlling Racial Prejudice: Social-Cognitive Goals Affect Amygdala and Stereotype Activation*, 16 PSYCHOL. SCI. 56, 56 (2005).

92. Holger Breithaupt & Katrin Weigmann, *Manipulating Your Mind: What Will Science Discover About Our Brains, and How Are We Going to Deal with It?* 5 EMBO REPORTS 230, 232 (2004) (“[S]tudies show[] that the brain reacts differently at first sight when seeing a person of the same or a different skin colour. That does not necessarily mean that everyone is a racist, but refinement of such methods could unveil personal prejudices or preferences.”) (citations omitted).

93. *All in the Mind: Racial Bias on the Brain* (Radio National radio broadcast Nov. 30, 2003), available at <http://www.abc.net.au/rn/science/mind/s997984.htm>.

94. David Adam, *Inside the Mind of a Racist: Scans May Reveal Brain’s Hidden Centres of Prejudice*, GUARDIAN, Nov. 17, 2003, available at http://www.guardian.co.uk/uk_news/story/0,3604,1086737,00.html.

95. Amanda Gardner, *Hiding Racial Bias Can Tax Brain*, HEALTHDAY, Dec. 11, 2003, available at <http://www.westernbaptist.com/news/healthscout/?id=516175>.

96. Press Release, New York University, *NYU/Yale Research Team Explores Neural Basis of Racial Evaluation*, Sept. 18, 2000, available at http://www.nyu.edu/publicaffairs/newsreleases/b_amygdala.shtml.

97. Phelps & Thomas, *supra* note 71, at 755.

98. *Id.* at 748.

ception.”⁹⁹ Because of the difficulty associated with admitting polygraph results into courtroom evidence due to the technology’s unreliability, the search has been on for a new and better method of lie detection.¹⁰⁰ In a study published in 2001, Sean Spence and his colleagues used fMRI to scan the brains of ten male subjects as they answered thirty-six questions including, “Have you made your bed today?” and “Have you taken a tablet today?”¹⁰¹ Finding that reaction times were significantly longer when the subjects were lying and that “there was reliable activation within specific regions of prefrontal cortex,”¹⁰² the study authors concluded that “by using a highly constrained behavioural protocol we may begin to delineate the cognitive components of deception in human subjects. fMRI may provide a feasible method for investigating their neural correlates.”¹⁰³

Daniel Langleben and his colleagues also used fMRI to examine the neural correlates of deception in 2001.¹⁰⁴ In their oft-cited study, the authors’ subjects held a 5-of-clubs playing card in their pocket and were told to deny that they held the card while their brains were being scanned.¹⁰⁵ After reviewing the resulting brain scans, the scientists concluded that “there is a neurophysiological difference between deception and truth at the brain activation level that can be detected with fMRI” and that “refinements of the paradigm design and image analysis methodology could . . . establish an activation pattern predictive of deception on an individual level.”¹⁰⁶

In a third study conducted in 2001, Tatia Lee and her colleagues hypothesized that the pattern of brain activation in malingerers—individuals who intentionally and falsely or fraudulently simulate or exaggerate physical or mental disease—“would provide unique markers for the detection of deception.”¹⁰⁷ Lee used fMRI to image the brain activations of six healthy male volunteers while they performed forced-choice memory tasks involving simulated malingering.¹⁰⁸ Lee found some initial evidence of the neural correlates of

99. D.D. Langleben et al., *Brain Activity During Simulated Deception: An Event-Related Functional Magnetic Resonance Study*, 15 *NEUROIMAGE* 727, 727 (2002) (citing OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *THE USE OF INTEGRITY TESTS FOR PRE-EMPLOYMENT SCREENING* (1990)).

100. See, e.g., Vicki Haddock, *Lies Wide Open: Researchers Say Technology Can Show When and How a Lie Is Created Inside the Brain*, *SAN FRAN. CHRON.*, Aug. 6, 2006, at E-1.

101. Sean A. Spence et al., *Behavioural and Functional Anatomical Correlates of Deception in Humans*, 12 *NEUROREPORT* 2849, 2849 (2001).

102. *Id.* at 2851.

103. *Id.* at 2852.

104. Langleben et al., *supra* note 99, at 728.

105. *Id.* at 729.

106. *Id.* at 731.

107. Tatia M.C. Lee et al., *Lie Detection by Functional Magnetic Resonance Imaging*, 15 *HUM. BRAIN MAPPING* 157, 157 (2002).

108. *Id.* at 158.

feigned memory impairment and concluded that she may have identified “some extremely significant preliminary markers that have the promise to enhance the development of valid and sensitive methods for the detection of malingering.”¹⁰⁹ Lee stated that future studies should attempt to distinguish different types of liars.¹¹⁰

Other scientists have built on the initial work of Spence, Langleben, Lee, and their colleagues.¹¹¹ In one among several recent studies, Christos Davatzikos and his colleagues used fMRI to correctly identify 99 percent of true and false responses, leading to their conclusion that “accurate clinical tests could be based on measurements of brain function with fMRI.”¹¹² In a second recent study, Langleben and his colleagues concluded that “fMRI, in conjunction with a carefully controlled query procedure, could be used to detect deception in individual subjects.”¹¹³ Following the publication of these studies, the media issued dozens of reports stating that fMRI is capable of accurate lie detection. BBC News’ headline—*Brain Scanner Is a Lie Detector*—was perhaps the most convincing.¹¹⁴ Others were strongly emphatic: *Don’t Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection*¹¹⁵ and *Are They Lying? Functional MRI Holds the Answer, Scientists Say*.¹¹⁶

Reports of government interest in fMRI have fueled speculation over the government’s desired use of the technology. For example, the Department of Homeland Security granted \$3.5 million to Lockheed Martin and Rutgers University to develop a lie detector,¹¹⁷ the Department of Defense Polygraph Institute requested funding pro-

109. *Id.* at 163.

110. *Id.*

111. See, e.g., C. Davatzikos et al., *Classifying Spatial Patterns of Brain Activity with Machine Learning Methods: Application to Lie Detection*, 28 *NEUROIMAGE* 663, 663 (2005); G. Ganis et al., *Neural Correlates of Different Types of Deception: An fMRI Investigation*, 13 *CEREBRAL CORTEX* 830, 830 (2003); F. Andrew Kozel et al., *A Pilot Study of Functional Magnetic Resonance Imaging Brain Correlates of Deception in Healthy Young Men*, 16 *J. NEUROPSYCHIATRY & CLINICAL NEUROSCIENCES* 295, 295 (2004); Frank Andrew Kozel et al., *A Replication Study of the Neural Correlates of Deception*, 118 *BEHAV. NEUROSCIENCE* 852, 852 (2004); Daniel D. Langleben et al., *Telling Truth from Lie in Individual Subjects with Fast Event-Related fMRI*, 26 *HUM. BRAIN MAPPING* 262, 262 (2005).

112. Davatzikos et al., *supra* note 111, at 663.

113. Langleben et al., *supra* note 111, at 262.

114. *Brain Scanner Is a Lie Detector*, BBC NEWS, Nov. 30, 2004, available at <http://news.bbc.co.uk/2/hi/health/4051211.stm>.

115. Steve Silberman, *Don’t Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection*, WIRED MAG., Jan. 2006, available at http://www.wired.com/wired/archive/14.01/lying_pr.html.

116. Univ. of Tex. Health Sci. Ctr. at San Antonio, *Are They Lying? Functional MRI Holds the Answer, Scientists Say*, NEWS, Apr. 19, 2002, available at <http://www.uthscsa.edu/opa/issues/new35-16/fMRI.html>.

117. Amy Ellis Nutt, *What Makes a Terrorist? Science Is Finding Out*, NEWHOUSE NEWS, Dec. 23, 2005, at A1.

posals investigating lie detection,¹¹⁸ and the Department of Defense Advanced Research Projects Agency is developing a “head web,” or a helmet that would conduct noninvasive brain monitoring of soldiers while in combat.¹¹⁹ Now, the question is whether government and criminal justice officials will attempt to use fMRI to determine whether criminal suspects and terrorists are engaging in deception.¹²⁰ Bioethicists, lawyers, and physicians have contributed to the speculation.¹²¹

Drawing the line between science and speculation is difficult in the context of fMRI lie detection because two companies—No Lie MRI, Inc. and Cephos Corp.—already have websites that identify a range of potential brain scanning uses.¹²² According to its website, No Lie MRI is currently marketing its brain scanning services to federal, state, and international governments, as well as a range of private companies.¹²³ Cephos Corporation stated in late December 2006 its intention to offer its brain scanning product as soon as its product meets its own internally established scientific standards.¹²⁴ Robert Shapiro, who is best known for defending O.J. Simpson in his double-murder case (and who has a financial interest in Cephos), says that he will use fMRI “‘tomorrow in virtually every criminal and civil case on my desk’ to check the truthfulness of clients.”¹²⁵ Perhaps in response to reports such as these, Langleben co-authored a paper in 2005 that stated, “Premature application of these technologies out-

118. Silberman, *supra* note 115.

119. Morgan Ratcliffe, *Author Shares Insight on Link Between Neuroscience, Government*, DAILY UTAH CHRON., Jan. 24, 2006, available at <http://www.dailyutahchronicle.com> (search “Author Shares Insight”; then follow hyperlink).

120. Jennifer Wild, *Brain Imaging Ready to Detect Terrorists, Say Neuroscientists*, 437 NATURE 457, 457 (2005); Beth W. Orenstein, *Guilty? Investigating fMRI's Future as a Lie Detector*, RADIOLOGY TODAY May 16, 2005, at 30.

121. TANCREDI, *supra* note 8, at 122 (“With the refinement of lie-detecting techniques, it is likely that they will be used extensively not only by law enforcement agencies, but possibly even schools and the health care system.”); Rosen, *supra* note 17 (“‘Officials who are examining the suspects could hook them up to an f.M.R.I. device, show them pictures of the battlefield in Afghanistan, and [ask them] if they’ve been in that particular place before’” (citation omitted)).

122. No Lie MRI, Inc., <http://www.noliemri.com> (last visited June 22, 2007) [hereinafter No Lie MRI]; Cephos Corp., <http://www.cephoscorp.com> (last visited June 22, 2007).

123. No Lie MRI, Inc., Customers: Government, <http://www.noliemri.com/customers/Government.htm> (last visited June 22, 2007) [hereinafter No Lie MRI: Government] (marketing brain scanning services directly to federal, state, and international governments); No Lie MRI, Inc., Customers: Corporate, <http://www.noliemri.com/customers/GroupOrCorporate.htm> (last visited June 22, 2007) [hereinafter No Lie MRI: Corporate] (marketing brain scanning services directly to employers, including security firms and investment firms, as well as insurance companies).

124. Cephos’ CEO Speaks on Commercial Testing, available at http://www.cephoscorp.com/cephos_comm_testing_20061215%20v2.pdf.

125. Malcolm Ritter, *Brain Scans as Lie Detectors? Our Own Lying Thief Checks It Out*, N. COUNTY TIMES (SAN DIEGO), Jan. 28, 2006, available at http://www.nctimes.com/articles/2006/01/29/science/17_00_211_28_06.txt.

side of research settings should be resisted, and the social conversation about the appropriate parameters of its civil, forensic, and security use should begin.”¹²⁶ However, the website of Langleben’s No Lie MRI continues to advertise its brain scanning product for these uses.¹²⁷

D. *Understanding Social Cooperation and Altruism*

For many years, evolutionary biologists, behaviorists, economists, and even political scientists have attempted to understand why cooperation (the act of working together to achieve a common aim) and altruism (the belief that acting for the benefit of others is right and good) exist, even though these acts and beliefs may not result in any direct or immediate reward to the cooperative or altruistic individual.¹²⁸ During the last decade, scientists have used fMRI in an attempt to better understand cooperative and altruistic behavior.

In one study involving two separate experiments conducted in 2002, James Rilling and his colleagues 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.¹²⁹ The study authors concluded that mutual cooperation was associated with consistent activation in regions of the brain linked to reward processing.¹³⁰ The scientists proposed that the pattern of neural activation positively reinforces reciprocal altruism, thereby motivating subjects to resist the temptation to act in their immediate self-interest by defecting.¹³¹

In a second study conducted in 2004, Rilling and his colleagues hypothesized “that reciprocated cooperation will increase the firing frequency of midbrain dopamine neurons, whereas unreciprocated cooperation will decrease the firing frequency.”¹³² The purpose of the study was to better understand the neural mechanism that allows

126. Paul Root Wolpe et al., *Emerging Neurotechnologies for Lie-Detection: Promises and Perils*, AM. J. BIOETHICS, Mar.-Apr. 2005, at 39, 39 (2005). See generally Ruth L. Fischbach & Gerald D. Fischbach, *The Brain Doesn’t Lie*, AM. J. BIOETHICS, Mar.-Apr. 2005, at 54, 55 (“We are not ready to turn away from the skin and the heart to rely on still mysterious and central mechanisms that correlate with a lie.”); Tom Buller, *Can We Scan for Truth in a Society of Liars?* AM. J. BIOETHICS, Mar.-Apr. 2005, at 58, 58 (“Nevertheless, emerging neurotechnologies present the type of threat to privacy discussed by the authors only if one believes that neuroscience can reveal the mind’s contents. . . . I do not share this belief.”).

127. No Lie MRI: Government, *supra* note 123; No Lie MRI: Corporate, *supra* note 123.

128. James K. Rilling et al., *A Neural Basis for Social Cooperation*, 35 NEURON 395, 395 (2002).

129. *Id.*

130. *Id.* at 397, 403.

131. *Id.*

132. See James K. Rilling et al., *Opposing BOLD Responses to Reciprocated and Unreciprocated Altruism in Putative Reward Pathways*, 15 NEUROREPORT 2539, 2539 (2004).

individuals to learn who is a good social partner and who is not, thereby protecting individuals from partnering with cheaters.¹³³ The scientists scanned the brains of nineteen subjects while they played a series of single-shot Prisoner's Dilemma games and found that reciprocated cooperation was associated with an increased BOLD response and that an unreciprocated cooperation was associated with a decreased BOLD response.¹³⁴ The scientists believe that the difference in BOLD response may teach individuals to partner with other individuals who reciprocate and to avoid individuals who do not reciprocate.¹³⁵

Following the publication of Rilling's first study in 2002, a *New York Times* reporter quoted one of Rilling's colleagues as stating, "If we put some C.E.O.'s in [an fMRI scanner], I'd like to see how they respond. . . . Maybe they wouldn't find a positive social interaction rewarding at all."¹³⁶ Perhaps prominent bioethicist Jonathan Moreno read the *Times* article; he speculated in 2003 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.¹³⁷

E. Understanding Sexual Arousal and Love

Functional MRI also has been used to study the neural correlates of sexual arousal as well as maternal and romantic love. Notwithstanding the common understanding of the brain as the "master organ" that governs sexual function, little has been known about the neural correlates of sexual arousal.¹³⁸ In an attempt to better understand this relationship, Bruce Arnow and his colleagues conducted a study in 2000 that used fMRI to examine the brains of fourteen heterosexual males aged eighteen to thirty years as they watched erotic, relaxing, and sports video material.¹³⁹ "[T]he erotic segments involved four types of sexual activities: rear entry intercourse, intercourse with the female in the superior position, fellatio and sexual intercourse with the male in the superior position."¹⁴⁰ A custom-built pneumatic pressure cuff was used to measure the subjects' penile

133. *Id.*

134. *Id.* at 2543.

135. *Id.*

136. Natalie Angier, *Why We're So Nice: We're Wired to Cooperate*, N.Y. TIMES, July 23, 2002, at F1.

137. Jonathan D. Moreno, *Neuroethics: An Agenda for Neuroscience and Society*, 4 NATURE REV. NEUROSCIENCE 149, 152 (2003).

138. Bruce A. Arnow et al., *Brain Activation and Sexual Arousal in Healthy, Heterosexual Males*, 125 BRAIN 1014, 1014 (2002).

139. *Id.* at 1015-16.

140. *Id.* at 1016.

turgidity while their brains were being scanned.¹⁴¹ The study authors observed strong brain activations associated with penile turgidity in the right insula/subinsular region of the subjects' brains and smaller, but still significant, activations in the subjects' hypothalamuses.¹⁴² Although they clarified that they could not draw any "causal conclusions regarding brain-behavior relationships" from their study, the scientists did state that their findings suggest "which regions of the brain, if damaged, might produce changes in sexual function."¹⁴³ The scientists hinted that future studies involving brain-damaged subjects might provide more information about "the precise roles of activated regions in sexual arousal."¹⁴⁴

Although romantic and maternal love are regarded as highly rewarding experiences and "are linked to the perpetuation of the species," very little has been known about their neural correlates.¹⁴⁵ In an attempt to better understand the neural correlates of romantic love, Andreas Bartels and Semir Zeki in 2000 used fMRI to image the brains of eleven female and six male volunteers who claimed to be "truly, deeply and madly in love" while they viewed images of the objects of their affections.¹⁴⁶ The scientists compared this brain activity to the activity that resulted when the volunteers viewed control images of "three friends of the same sex as their loved partner."¹⁴⁷ The scientists concluded from their findings that a unique network of areas are associated with romantic love.¹⁴⁸

In an attempt to better understand the neural correlates of maternal love, Bartels and Zeki conducted a second study in 2003 that used fMRI to measure brain activity in twenty mothers aged twenty-seven to forty-nine while they viewed pictures of their own children as well as control images of other children.¹⁴⁹ The scientists then compared the maternal brain activations to those associated with romantic love from their 2000 study, finding that both types of attachment activated areas of the brain specific to each, as well as overlapping areas in the brain's reward system that coincide with areas rich in oxytocin and vasopressin receptors.¹⁵⁰ The scientists also found that both romantic and maternal love deactivated a common

141. *Id.*

142. *Id.* at 1019-20.

143. *Id.* at 1021.

144. *Id.* at 1021-22.

145. Andreas Bartels & Semir Zeki, *The Neural Correlates of Maternal and Romantic Love*, 21 *NEUROIMAGE* 1155, 1155 (2004).

146. Andreas Bartels & Semir Zeki, *The Neural Basis of Romantic Love*, 11 *NEUROREPORT* 3829, 3829 (2000).

147. *Id.*

148. *See id.* at 3831.

149. Bartels & Zeiki, *supra* note 145, at 1155-56.

150. *Id.* at 1161-62.

set of regions associated with negative emotions, social judgment, and the assessment of other people's intentions and emotions.¹⁵¹ The scientists concluded that human attachment bonds individuals through a "push-pull mechanism" that deactivates networks used for critical social assessment and negative emotions while triggering mechanisms involved in reward.¹⁵² Picking up on both the romantic and maternal love studies, the media has reported that *Science Unlocks Secrets of the Elixir of Love*¹⁵³ and *Love Makes You Light Up—Even in Your Brain, Researchers Say*.¹⁵⁴

Scientists continue to study the neural correlates of love and sexual arousal,¹⁵⁵ as well as sexual preferences. In a study published in 2006, Felicitas Kranz and Alomit Ishai hypothesized that heterosexual and homosexual subjects would exhibit a greater response in the reward circuitry to faces deemed sexually preferable.¹⁵⁶ To test their hypothesis, the study authors used fMRI to scan the brains of forty subjects—ten heterosexual women, ten heterosexual men, ten homosexual women, and ten homosexual men—as they viewed faces of individuals of different genders.¹⁵⁷

Consistent with their hypothesis, the authors found that the gender of a viewed individual, when the sexual preference of the subject was taken into account, did make a difference in the reactions seen in the thalamus and the orbitofrontal cortex, a region of the brain's reward circuitry.¹⁵⁸ Heterosexual women and homosexual men exhibited a significantly greater response to male faces, whereas heterosexual men and homosexual women responded significantly more to female faces.¹⁵⁹ The scientists concluded that the brain's response to faces in the reward circuitry is modulated by sexual preference and that there is neural evidence for the role of face processing in mating.¹⁶⁰

Following publication of Kranz's and Ishai's study, news magazines and blogs reported that *Gays Read Faces Differently than*

151. *Id.* at 1163.

152. *Id.* at 1162-64.

153. Chris Ayres, *Science Unlocks Secrets of the Elixir of Love*, TIMES (London), Mar. 13, 2004, available at <http://www.sensualism.com/love/elixir.html>.

154. *Love Makes You Light Up—Even in Your Brain, Researchers Say*, CNN.COM, Nov. 8, 2000, <http://archives.cnn.com/2000/HEALTH/11/08/love.in.lights.ap/index.html>.

155. See, e.g., Arthur Aron et al., *Reward, Motivation and Emotion Systems Associated with Early-Stage Intense Romantic Love*, 94 J. NEUROPHYSIOLOGY 327, 327 (2005); Gwang-Woo Jeong et al., *Assessment of Cerebrocortical Regions Associated with Sexual Arousal in Premenopausal and Menopausal Women by Using BOLD-Based Functional MRI*, 2 J. SEXUAL MED. 645, 645 (2005); Ivanka Savic et al., *Brain Response to Putative Pheromones in Homosexual Men*, 102 PROC. NAT'L ACAD. SCI. 7356, 7356 (2005).

156. Felicitas Kranz & Alomit Ishai, *Face Perception Is Modulated by Sexual Preference*, 16 CURRENT BIOLOGY 63, 63 (2006).

157. *Id.* at 66-67.

158. *Id.* at 63.

159. *Id.*

160. *Id.* at 64-66.

*Straights*¹⁶¹ and *Gay Brains Respond Differently to Faces than Straight Brains*.¹⁶² These headlines add to prior speculation that the government and other organizations might want to use fMRI to test soldiers and members for homosexuality or unconscious sexual impulses and to discharge such individuals based upon “positive” test results.¹⁶³

F. *Understanding Ethical Decision Making*

Functional MRI also has been used to study the neural correlates of ethical decision making, including the decisions required by the classic, two-scenario trolley problem. In the trolley problem, a runaway train is approaching five people on a track.¹⁶⁴ In the first scenario, all five people on the track will die unless an individual pulls a lever that will move the train onto a second track, on which a sole person is standing.¹⁶⁵ If the individual pulls the lever and diverts the train onto the second track, the person on the second track will be killed but the five people will be saved.¹⁶⁶ The question is, what should the individual do and why? Most people would say that the individual ought to pull the lever and save five lives at the expense of one.¹⁶⁷ In the second scenario, an individual is standing on a footbridge overlooking the same track.¹⁶⁸ Right next to the individual on the footbridge is a man who is overweight.¹⁶⁹ If the individual pushes the man onto the track, the individual will stop the train and save five people, although the man who is overweight will be killed.¹⁷⁰ Again, the question is, what should the individual do and why?

Many people believe that it is morally acceptable to pull the lever in the first scenario, but not to push the man who is overweight to his death in the second scenario. Although the logic in both cases is the same, some have described the difference as the emotional closeness, or the “up close and personal” nature, of the second action com-

161. Bob Roehr, *Gays Read Faces Differently than Straights*, IN NEWSWEEKLY, Jan. 11, 2006, available at http://www.innewsweekly.com/innews/?class_code=He&article_code=1120.

162. Posting of Andy to Eleventh Avenue South, *Gay Brains Respond Differently to Faces than Straight Brains*, <http://www.eleventh-avenue-south.com/archives/000676.html> (Jan. 16, 2006, 21:20 CST).

163. Austin Cline, *Brain Privacy: Are Your Thoughts Safe? MRIs Revealing More than Even You Know About Yourself*, ABOUT, http://atheism.about.com/library/FAQs/phil/blphil_ethbio_brainpriv.htm (last visited June 22, 2007).

164. Roskies, *supra* note 1, at 21.

165. *Id.*

166. *Id.*

167. *Id.*

168. Marc Hauser et al., *A Dissociation Between Moral Judgments and Justifications*, 22 MIND & LANGUAGE 1, 6-7 (2007).

169. *Id.*

170. *Id.*

pared to the relative distancing of the first.¹⁷¹ Stated another way, the thought of directly pushing someone to his death may be more “emotionally salient” than the thought of hitting a switch that will cause a trolley to produce similar consequences.¹⁷²

Joshua Greene and his colleagues decided to test this hypothesis using fMRI in 2001.¹⁷³ Greene found that, when confronted by the second scenario, his subjects’ fMRI scans showed activation in areas associated with the emotions of sadness, fright or general uneasiness—areas that were not activated by the first scenario.¹⁷⁴ Although Greene concluded that the emotional response was the crucial difference between the two scenarios, he emphasized in his published study that his conclusion was descriptive, rather than prescriptive, and that he was not claiming to have shown that any actions or judgments were morally right or wrong.¹⁷⁵ However, several news reports announced Greene’s research findings using headlines such as *Cerebral Scans for Right and Wrong* and *Brain Imaging Sheds Light on Moral Decision-Making*.¹⁷⁶ Scientists continue to use fMRI to study the areas of the brain that are activated during ethical and moral decision making.¹⁷⁷

G. Neuromarketing

Functional MRI also has been used to examine preferences regarding consumer goods and services such as automobiles,¹⁷⁸ soft drinks,¹⁷⁹ campaign advertisements,¹⁸⁰ and the content of movie trail-

171. Phineas Gage Group, How Do the Emotional and Rational Parts of the Brain Interrelate?, <http://www.phineasgagroup.org/?cat=91> (last visited June 22, 2007) [hereinafter Phineas Gage Group]. See also Jonathan D. Cohen, M.D., Ph.D., Professor of Psychology and Director, Center for the Study of Brain, Mind and Behavior, Princeton University, Testimony Before the President’s Council on Bioethics (Jan. 15, 2004) (transcript available at <http://bioethicsprint.bioethics.gov/transcripts/jan04/session4.html>); Joshua D. Greene et al., *An fMRI Investigation of Emotional Engagement in Moral Judgment*, 293 SCI. 2105, 2106 (2001).

172. *Id.*

173. *Id.* at 2105-08.

174. Phineas Gage Group, *supra* note 171.

175. *Id.* at 2107.

176. Ronald Bailey, *Morality on the Brain: Cerebral Scans for Right and Wrong*, REASONONLINE, Jan. 27, 2006, <http://www.reason.com/rb/rb012706.shtml>; *Brain Imaging Study Sheds Light on Moral Decision-Making*, SCI. DAILY, Sept. 14, 2001, available at <http://www.sciencedaily.com/releases/2001/09/010914074303.htm>.

177. See, e.g., ANTONIO DAMASIO, LOOKING FOR SPINOZA: JOY, SORROW, AND THE FEELING BRAIN (2003); GAZZANIGA, *supra* note 8; Hauke R. Heekeren et al., *An fMRI Study of Simple Ethical Decision-Making*, 14 NEUROREPORT 1215, 1215 (2003); Jorge Moll et al., *The Neural Correlates of Moral Sensitivity: A Functional Magnetic Resonance Imaging Investigation of Basic and Moral Emotions*, 22 J. NEUROSCIENCE 2730, 2730 (2002).

178. Susanne Erk et al., *Cultural Objects Modulate Reward Circuitry*, 13 NEUROREPORT 2499, 2499 (2002).

179. Samuel M. McClure et al., *Neural Correlates of Behavioral Preference for Culturally Familiar Drinks*, 44 NEURON 379, 379 (2004).

ers¹⁸¹—in part to help manufacturers and marketing companies determine the best way to market certain products and services. In one study sponsored by DaimlerChrysler in 2002, Susanne Erk and her colleagues used fMRI to study the rewarding properties of cars that signaled wealth and social dominance.¹⁸² Erk hypothesized that sports cars—in contrast to other cars such as small cars and even limousines—would activate the reward circuitry in the brain.¹⁸³ To test her hypothesis, Erk asked twelve healthy male subjects to view different classes of cars while having their brains scanned.¹⁸⁴ Erk observed significantly more activation in reward-related areas of the brain for sports cars in contrast to other categories of cars, thus leading to her conclusion that “artificial cultural objects associated with wealth and social dominance elicit activation in reward-related brain areas.”¹⁸⁵

In a second neuromarketing study, Samuel McClure and his colleagues used fMRI to examine the neural correlates underlying soft-drink preferences and their influence by cultural images.¹⁸⁶ When brain images were acquired during the subjects’ blind taste-test of Coke and Pepsi, McClure found activity in an area of the brain that is “implicated in signaling basic appetitive aspects of reward.”¹⁸⁷ When brain images were acquired when the subjects were told that they were drinking Coke, areas of the brain known to be “implicated in modifying behavior based on emotion and affect” were activated.¹⁸⁸ When brain images were acquired when the subjects were told that they were drinking Pepsi, the same activations were not observed.¹⁸⁹ McClure concluded that brand knowledge of Coke dramatically influenced certain brain activations.¹⁹⁰

In a third neuromarketing study conducted at UCLA in 2004, scientists used fMRI to study the brain reaction of known Republican and Democrat voters who were shown campaign advertisements that included images of the September 11, 2001, terrorist attacks.¹⁹¹ The UCLA scientists found that the campaign advertisements caused the amygdala—an area of the brain known to be associated with fear and

180. John Tierney, *Using M.R.I.'s to See Politics on the Brain*, N.Y. TIMES, Apr. 20, 2004, at A1.

181. *Inside the Mind of the Consumer*, ECONOMIST, June 12, 2004, at 12.

182. Erk et al., *supra* note 178, at 2499, 2503.

183. *Id.* at 2499.

184. *Id.*

185. *Id.*

186. McClure et al., *supra* note 179, at 379.

187. *Id.* at 384.

188. *Id.* at 385.

189. *Id.*

190. *Id.*

191. Tierney, *supra* note 180.

anger—to light up more vividly in Democrats than in Republicans.¹⁹² Although the scientists warned against drawing conclusions about the ability of fMRI to help with political campaigns until they had experimented with a greater number of subjects, news reports referenced the study when speculating that fMRI will help candidates rely less on campaign clichés and more on “scientific” advertising.¹⁹³

In addition to automobiles, soft drinks, and campaign and product advertisements,¹⁹⁴ fMRI also has been used to study the marketability of movie trailers and beautiful female faces.¹⁹⁵ Companies on both sides of the Atlantic—the Brighthouse Institute for Thought Sciences in Atlanta, FKF Applied Research in Los Angeles, and the UK’s Neurosense/Neuromarketing Consultancy—have claimed they can use fMRI and the principles of cognitive neuroscience to gain insight into human behaviour.¹⁹⁶ Not surprisingly, the media has picked up on fMRI’s neuromarketing potential to ask whether the brain has a “buy button,” to discuss the “science of shopping” and the “why of buy,” and to “probe the minds of consumers.”¹⁹⁷

H. Other fMRI Studies

This Part presents a few popular fMRI studies that have generated significant speculation regarding their application in non-research contexts. Functional MRI also has been used to study the neural correlates of stroke,¹⁹⁸ multiple sclerosis,¹⁹⁹ Parkinson’s disease,²⁰⁰ Alzheimer’s disease,²⁰¹ major depression,²⁰² schizophrenia,²⁰³

192. *Id.*

193. *Id.*

194. See, e.g., Marco Iacoboni, *Who Really Won the Superbowl? The Story of an Instant-Science Experiment*, EDGE, Jan. 2006, http://www.edge.org/3rd_culture/iacoboni06/iacoboni06_index.html (last visited June 22, 2007); Stefanie Olsen, *This Is Your Brain on a Super Bowl Ad*, CNET NEWS.COM, Feb. 7, 2006, http://news.com.com/2100-1024_3-6036456.html.

195. Sandra Blakeslee, *If You Have a ‘Buy Button’ in Your Brain, What Pushes It?*, N.Y. TIMES, Oct. 19, 2004, at F5.

196. Iacoboni, *supra* note 194; Neurosense, About Neurosense, <http://www.neurosense.com/about.html> (last visited June 22, 2007); Edwin Colyer, The Science of Branding, Brandchannel.com, http://www.brandchannel.com/features_effect.asp?pf_id=201 (Mar. 15, 2004) (referencing BrightHouse Institute for Thought Sciences press release that stated, “Thought Sciences marketing analysts use [fMRI] . . . information to more accurately measure consumer preference” (alteration in original)).

197. Blakeslee, *supra* note 195; Margo Kelly, *The Science of Shopping*, CBC NEWS, Dec. 2, 2002, http://www.cbc.ca/consumers/market/files/money/science_shopping/; Eric Roston, *The Why of Buy*, TIME, Feb. 29, 2004, available at <http://www.time.com/time/insidebiz/article/0,9171,1101040308-596161,00.html>.

198. Cornelius Weiller et al., *Role of Functional Imaging in Neurological Disorders*, 23 J. MAGNETIC RESONANCE IMAGING 840, 841 (2006).

199. *Id.* at 842.

200. *Id.* at 845.

201. Alexandra Golby et al., *Memory Encoding in Alzheimer’s Disease: An fMRI Study of Explicit and Implicit Memory*, 128 BRAIN 773, 773 (2005).

bipolar disorder,²⁰⁴ obsessive-compulsive disorder,²⁰⁵ dyslexia and hyperlexia,²⁰⁶ attention-deficit/hyperactivity disorder,²⁰⁷ pedophilia,²⁰⁸ cocaine addiction,²⁰⁹ compulsive gambling,²¹⁰ expected and unexpected pleasure,²¹¹ satiety and obesity,²¹² anxiety,²¹³ neuroticism,²¹⁴ extraversion,²¹⁵ self-consciousness,²¹⁶ physical pain,²¹⁷ migraines and cluster headaches,²¹⁸ social rejection,²¹⁹ intelligence,²²⁰ humanity,²²¹

202. Avram J. Holmes et al., *Prefrontal Functioning During Context Processing in Schizophrenia and Major Depression: An Event-Related fMRI Study*, 76 SCHIZOPHRENIA RES. 199, 199 (2005); Dobbs, *supra* note 67.

203. Cherine Fahim et al., *Brain Activity During Emotionally Negative Pictures in Schizophrenia With and Without Flat Effect: An fMRI Study*, 140 PSYCHIATRY RES.: NEUROIMAGING 1, 1 (2005); Rachel L.C. Mitchell et al., *Neural Response to Emotional Prosody in Schizophrenia and in Bipolar Affective Disorder*, 184 BRIT. J. PSYCHIATRY 223, 223 (2004).

204. Mitchell et al., *supra* note 203, at 223.

205. Martina T. Mitterschiffthaler et al., *Applications of Functional Magnetic Resonance Imaging in Psychiatry*, 23 J. MAGNETIC RESONANCE IMAGING 851, 854 (2006).

206. Serge Ruff et al., *Neural Substrates of Impaired Categorical Perception of Phonemes in Adult Dyslexics: An fMRI Study*, 53 BRAIN & COGNITION 331, 331 (2003); Peter E. Turkeltaub et al., *The Neural Basis of Hyperlexic Reading: An fMRI Case Study*, 41 NEURON 11, 11 (2004); Gina Kolata, *Scientists Track the Process of Reading Through the Brain*, N.Y. TIMES, Mar. 3, 1998, at F3.

207. George Bush et al., *Functional Neuroimaging of Attention-Deficit/Hyperactivity Disorder: A Review and Suggested Future Directions*, 57 BIOLOGICAL PSYCHIATRY 1273, 1273 (2005).

208. Harald Dressing et al., *Homosexual Pedophilia and Functional Networks—An fMRI Case Report and Literature Review*, 69 FORTSCHRITTE DER NEUROLOGIE-PSYCHIATRIE 539, 539 (2001).

209. Hans C. Breiter et al., *Acute Effects of Cocaine on Human Brain Activity and Emotion*, 19 NEURON 591, 591 (1997); *Precise Effects of Cocaine Are Seen in Brain Scans*, N.Y. TIMES, Sept. 26, 1997, at A18.

210. David N. Crockford et al., *Cue-Induced Brain Activity in Pathological Gamblers*, 58 BIOLOGICAL PSYCHIATRY 787, 787 (2005).

211. Gregory S. Berns et al., *Predictability Modulates Human Brain Response to Reward*, 21 J. NEUROSCIENCE 2793, 2793 (2001); Eric Nagourney, *Surprise! Brain Likes Thrill of Unknown*, N.Y. TIMES, Apr. 17, 2001, at F6.

212. G. Andrew James et al., *Imaging In Vivo Brain-Hormone Interaction in the Control of Eating and Obesity*, 3 DIABETES TECH. & THERAPEUTICS 617, 617 (2001).

213. Ahmad R. Hariri et al., *Serotonin Transporter Genetic Variation and the Response of the Human Amygdala*, 297 SCI. 400, 400 (2002); Eric Nagourney, *Fearing More than Fear Itself*, N.Y. TIMES, July 30, 2002, at F6.

214. Naomi I. Eisenberger et al., *Personality from a Controlled Processing Perspective: An fMRI Study of Neuroticism, Extraversion, and Self-Consciousness*, 5 COGNITIVE, AFFECTIVE, & BEHAV. NEUROSCIENCE 169, 169 (2005).

215. *Id.*

216. *Id.*

217. Alexander Ploghaus et al., *Dissociating Pain from Its Anticipation in the Human Brain*, 284 SCI. 1979, 1979 (1999); Melanie Thernstrom, *My Pain, My Brain*, N.Y. TIMES, May 14, 2006, § 6, at 50.

218. Weiller et al., *supra* note 198, at 846.

219. Naomi I. Eisenberger et al., *Does Rejection Hurt? An fMRI Study of Social Exclusion*, 302 SCI. 290, 290 (2003).

220. Jeremy R. Gray et al., *Neural Mechanisms of General Fluid Intelligence*, 6 NATURE REV. NEUROSCIENCE 316, 316 (2003); Jeremy R. Gray & Paul M. Thompson, *Neurobiology of Intelligence: Science and Ethics*, 5 NATURE REV. NEUROSCIENCE 471, 471

empathy (or lack thereof),²²² trust,²²³ humor,²²⁴ recognition of beauty²²⁵ and, even, the differences in the way men's and women's brains function when they are thinking.²²⁶ Approximately 10,000 fMRI studies have been conducted since the technology's introduction in the early 1990s.²²⁷

I. fMRI Hype

This Part shows that although many of the scientists who conduct neuroimaging studies use care when publishing their findings—and even caution readers against inappropriate or too eager interpretations and applications—the descriptions of neuroimaging research in the popular media (including physicians', lawyers', bioethicists', and scientists' statements to the media) are not as constrained.²²⁸ The public must wade through reports suggesting that fMRI is (or soon will be) capable of completely transforming neurosurgical interventions, identifying individuals' racial preferences and prejudices, determining deception on an individual level, selecting socially cooperative or competitive individuals from among a pool of applicants, and recognizing whether an individual is heterosexual or homosexual, capable of making moral and ethical decisions, or prefers a particular consumer product. The public is increasingly confronted with reports that racial evaluation, deception, maternal and romantic love, violence, and mental disorders are “hardwired” in the brain, despite scientists' published statements that their research simply examines the neural correlates of such conditions and behaviors.²²⁹ Notwithstanding many scientists' attempts to clarify their research findings

(2004); Erica Goode, *Brain Scans Reflect Problem-Solving Skill*, N.Y. TIMES, Feb. 17, 2003, at A14.

221. Sandra Blakeslee, *Humanity? Maybe It's in the Wiring*, N.Y. TIMES, Dec. 9, 2003, at F1.

222. Tania Singer et al., *Empathic Neural Responses Are Modulated by the Perceived Fairness of Others*, 439 NATURE 466, 466 (2006); James Gorman, *This Is Your Brain on Schadenfreude. Do You Feel Bad About Feeling Good?* N.Y. TIMES, Jan. 24, 2006, at F3.

223. Brooks King-Casas et al., *Getting to Know You: Reputation and Trust in a Two-Person Economic Exchange*, 308 SCI. 78, 78 (2005); Henry Fountain, *Study of Social Interactions Starts with a Test of Trust*, N.Y. TIMES, Apr. 1, 2005, at A20.

224. Glenn Collins, *Scientists Try to Find Out What's So Funny About Humor*, N.Y. TIMES, Sept. 28, 2004, at F3.

225. Penelope Green, *Mirror, Mirror; Biologically Speaking, Isn't She Beautiful?*, N.Y. TIMES, Feb. 28, 1999, § 9, at 1.

226. Bennett A. Shaywitz et al., *Sex Differences in the Functional Organization of the Brain for Language*, 373 NATURE 607, 607 (1995); Gina Kolata, *Man's World, Woman's World? Brain Studies Point to Differences*, N.Y. TIMES, Feb. 28, 1995, at 1 (noting that the authors stressed “extreme caution in drawing conclusions from the data”).

227. Norris, *supra* note 12, at 794; Jezzard & Buxton, *supra* note 41, at 789.

228. Cf. Mark A. Rothstein, *Applications of Behavioural Genetics: Outpacing the Science?*, 6 NATURE REV. GENETICS 793, 793 (2005) (identifying a similar phenomenon in genetics research).

229. Cf. *id.* (identifying a similar effect in genetics); TANCREDI, *supra* note 8, at 11.

and identify appropriate and inappropriate uses of fMRI, the public—as well as employers, insurers, educators, marketing companies, judges, criminal justice officials, and government officials—still may be confused regarding what is science and what is speculation.²³⁰

Add to this confusion the pressures faced by individuals and organizations to obtain information that will optimize decision making. Neurosurgeons are under pressure to preserve brain function during surgery. Psychiatrists are under pressure to distinguish individuals who have schizophrenia from individuals who have bipolar disorder, because these two groups of individuals may respond to different treatments.²³¹ Health and life insurers are under pressure to underwrite only the healthiest individuals. Employers are under pressure to hire only the most productive applicants. Educational institutions are under pressure to admit only the most qualified students, and marketing companies are under pressure to advertise their clients' products in the most cost-efficient manner. Judges want to convict only those individuals who have actually committed crimes, criminal justice officials want to reduce jail and prison overcrowding by freeing those individuals who will behave appropriately during probation, and government officials want to identify which individuals will commit terrorist acts to prevent another September 11. Viewed in light of these pressures, the extensive speculation regarding fMRI's nonresearch applications is better understood.

Because of the potential for functional neuroimaging information to be used in nonresearch contexts, scientists need to continue the care with which they describe their research findings and the diligence with which they identify appropriate and inappropriate uses of neuroimaging information.²³² Private and governmental organizations that are legally permitted²³³ to conduct fMRI tests or obtain neuroimaging test results should first consult with scientists who conduct functional neuroimaging studies to ensure that they understand the limitations of neuroimaging research and the meaning of

230. See generally Timothy Caulfield, *Popular Media, Biotechnology, and the "Cycle of Hype,"* 5 HOUS. J. HEALTH L. & POL'Y 213 (2005) (describing media representations of biotechnology and the "cycle of hype" that exists in the genetics and stem cell research contexts); Rothstein, *supra* note 228, at 793 (finding that the public continues to be confused regarding genetics research).

231. See, e.g., Mental Illness Research, Education and Clinical Center, *VA Program Studies Brain Activity*, MINDVIEW, Winter 2000, at 1, 3 (noting that research has found malfunctions in the left side of the brain in schizophrenia and the right side of the brain in bipolar disorder and that individuals with schizophrenia and bipolar disorder respond to different treatments).

232. See Rothstein, *supra* note 228, at 797.

233. Parts IV, V, and VI, *infra*, discuss some of the legal barriers to the creation and use of, and access to, functional neuroimaging information.

fMRI test results.²³⁴ And, because functional neuroimaging information can be sensitive and stigmatizing, individuals who create, obtain, or use such information must protect its confidentiality and respect the privacy and identity of the individuals to whom the information relates.

J. Definitions

With this background, I now turn to fMRI's confidentiality, privacy, and identity implications,²³⁵ although I first must define *confidentiality*, *privacy*, and *identity*. The literature contains no shortage of relevant definitions (or lack of understanding thereof).²³⁶ Yet an-

234. See Hank T. Greely & Judy Illes, *Neuroscience-Based Lie Detection: The Urgent Need for Regulation*, 33 AM. J.L. & MED. (forthcoming 2007) (arguing that the federal government (or, barring that, state governments) should ban any nonresearch uses of new methods of lie detection, including specifically fMRI-based lie detection, unless or until the method has proven safe and effective to the satisfaction of a regulatory agency and has been vetted through the peer-reviewed scientific literature); Rothstein, *supra* note 228, at 797 (arguing that commercial and social institutions need to "consult with experts before applying behavioural genetics to avoid limiting opportunities for individuals or stigmatizing them").

235. Confidentiality, privacy, and identity issues have a history rich in ethics and law. Ancient and modern codes of medical and research ethics established both rights and duties relating to confidentiality and privacy. See, e.g., LUDWIG EDELSTEIN, *THE HIPPOCRATIC OATH: TEXT, TRANSLATION AND INTERPRETATION* 3 (1943); AM. MED. ASS'N, *CODE OF MED. ETHICS*, Op. E-5.059 (2001). Legal rights to privacy in the United States initially derived from property rights, although they began to develop through tort law at the end of the nineteenth century. See *Pavesich v. New England Life Ins. Co.*, 50 S.E. 68, 69 (Ga. 1905); Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 196, 204-05 (1890); *DeMay v. Roberts*, 9 N.W. 146, 149 (Mich. 1881). By the second half of the twentieth century, the common law of most jurisdictions recognized four distinct privacy torts—*intrusion*, *disclosure*, *false light*, and *appropriation*—as well as a common law right to confidentiality in the medical context. William L. Prosser, *Privacy*, 48 CAL. L. REV. 383, 389-423 (1960); see also RESTATEMENT (SECOND) OF TORTS, §§ 652A-E (1977). Beginning in the late nineteenth century, legal rights to privacy also developed through the Fourth as well as the First, Third, Fifth, Ninth, and Fourteenth Amendments to the U.S. Constitution and through their state law counterparts. See, e.g., *Boyd v. United States*, 116 U.S. 616, 630 (1886). Today, federal and state legislatures and administrative agencies continue to adopt statutes and regulations addressing confidentiality and privacy. See, e.g., 45 C.F.R. pt. 164 (2006).

236. See, e.g., William M. Beaney, *The Right to Privacy and American Law*, 31 L. & CONTEMP. PROBS. 253, 255 (1966) ("[E]ven the most strenuous advocate of a right to privacy must confess that there are serious problems of defining the essence and scope of this right."); Gaia Bernstein, *Accommodating Technological Innovation: Identity, Genetic Testing and the Internet*, 57 VAND. L. REV. 965, 973 (2004) (identity is a "multi-faceted and elusive" concept); Jonathan Kahn, *Privacy as a Legal Principle of Identity Maintenance*, 33 SETON HALL L. REV. 371, 371 (2003) ("The meaning of privacy . . . has proven elusive."); Judith Jarvis Thomson, *The Right to Privacy*, 4 PHIL. & PUB. AFF. 295, 295 (1975) ("Perhaps the most striking thing about the right to privacy is that nobody seems to have any very clear idea what it is."); William J. Winslade, *Confidentiality*, in *ENCYCLOPEDIA OF BIOETHICS* 194, 195-96 (Warren T. Reich et al. ed., 1978) (noting that confidentiality has "blurred edges" and that the concepts of confidentiality and privacy are "elastic," "vague," and "easily confused"); Sheri A. Alpert, *Protecting Medical Privacy: Challenges in the Age of Genetic Information*, 59 J. SOC. ISSUES 301, 302 (2003) (noting various definitions of privacy).

other attempt to define these terms will not meaningfully add to this literature. Accordingly, I use the word *confidentiality* to mean the obligation of an individual or organization to prevent the unauthorized or otherwise inappropriate use or disclosure of appropriately gathered functional neuroimaging information.²³⁷ Confidentiality issues raised by fMRI include the appropriateness of various uses and disclosures of functional neuroimaging information by physicians, scientists, hospitals, imaging centers, and academic medical centers.

I use the word *privacy* more broadly to include an individual's interest in avoiding the unwanted collection of her functional neuroimaging information by a third party.²³⁸ Relevant privacy issues include an individual's interest in preventing health care providers, scientists, insurance companies, employers, educational institutions, the government, criminal justice officials, courts, litigants, and marketing companies from gathering neuroimaging information relating to the individual other than information voluntarily disclosed by the individual.

Finally, I use the word *identity* to refer to an individual's life narrative. By life narrative, I mean the ways in which individuals see themselves, illustrated in part by the unique stories that they tell themselves and others about themselves.²³⁹ Identity issues raised in the functional neuroimaging context include the potential of fMRI to reveal back to an individual one or more stories that are inconsistent with the individual's dominant life narrative.

IV. CONFIDENTIALITY

I will assume that most scientists and physicians respect their subjects' and patients' confidentiality rights and would not inappropriately use or disclose their brain scans and related interpretations. Notwithstanding these assumptions, I documented in Part III the speculation that functional neuroimaging information created by scientists and providers will leak beyond the research and clinical contexts and become available to employers, insurers, and others for use in hiring, firing, underwriting, and similar business decisions. Accordingly, I explore in this Part both traditional and unique confidentiality issues raised by various uses and disclosures of functional neuroimaging information under a selection of relevant legal authorities. Unique confidentiality issues raised by functional neuroimaging, including the inadvertent disclosure of facial images and the

237. See, e.g., Henry T. Greely, *Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience*, in *NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE* 114, 143 (Brent Garland ed., 2004).

238. *Id.*

239. ARTHUR W. FRANK, *THE WOUNDED STORYTELLER: BODY, ILLNESS, AND ETHICS* 75 (1995); Bernstein, *supra* note 236, at 974.

questions raised by incidental findings, are discussed under the authorities that are particularly relevant, with the recognition that similar analyses could be made under other authorities.

A. *The Common Rule*

Functional MRI is frequently used as a tool for investigations in human cognitive neuroscience.²⁴⁰ The regulations that apply most directly to investigations involving human subjects are the Protection of Human Subjects regulations (the Common Rule), the first version of which was published by the Federal Department of Health, Education, and Welfare in 1974.²⁴¹ Today, the Common Rule regulates all research involving human subjects that receive federal financial support from a signatory federal agency,²⁴² “research conducted in contemplation of a submission to the Food and Drug Administration [FDA] for approval,” and human subjects research conducted by an institution that has signed a multiple project assurance, which is an institutional promise “to comply with the Common Rule in all research, regardless of the funding source.”²⁴³ Most, but not all, scientists are federally funded, working under a multiple project assurance, or submitting projects to the FDA. The Common Rule and its confidentiality protections thus will apply to most, but not all, fMRI research.

When the Common Rule does apply to a particular fMRI study, an institutional review board (IRB) must review and approve the protocol in accordance with certain criteria²⁴⁴ that were established to protect the welfare of human subjects²⁴⁵ One criterion requires the IRB to determine that adequate protections exist to maintain the confidentiality of research data.²⁴⁶ An additional provision requires the informed consent documentation signed by the research subject to describe the extent to which confidentiality of records identifying the subject will be maintained.²⁴⁷ A third provision permits an IRB to waive the requirement for the investigator to obtain a signed consent form if the IRB finds “[t]hat the only record linking the subject and

240. John A. Detre, *Clinical Applicability of Functional MRI*, 23 J. MAGNETIC RESONANCE IMAGING 808, 808 (2006).

241. Protection of Human Subjects, 39 Fed. Reg. 18,914 (May 30, 1974) (codified as amended at 45 C.F.R. pt. 46).

242. Stacey A. Tovino, *The Use and Disclosure of Protected Health Information for Research Under the HIPAA Privacy Rule: Unrealized Patient Autonomy and Burdensome Government Regulation*, 49 S.D. L. REV. 447, 448 n.8 (2004) (listing the federal agencies that are signatories to the Common Rule).

243. 45 C.F.R. § 46.101(a) (2006); Mark A. Rothstein, *Research Privacy Under HIPAA and the Common Rule*, 33 J.L. MED. & ETHICS 154, 155 (2005).

244. 45 C.F.R. § 46.111 (2006).

245. Rothstein, *supra* note 243, at 155.

246. 45 C.F.R. § 46.111(a)(7).

247. *Id.* § 46.111(a)(5), -.116(a)(5), -.117.

the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.”²⁴⁸ In this case, the subject shall be asked whether she wants documentation linking her with the research, and her wishes shall govern.²⁴⁹

These three provisions are the only provisions in the Common Rule that address confidentiality in human subjects research, and HHS has not provided significant guidance regarding their design, interpretation, and application. HHS has generally interpreted the “adequate provisions” language in the first provision to require investigators to “replace[] names and other identifiers with codes and [to] store[] paper and electronic research records securely.”²⁵⁰ HHS commentary published in the *Federal Register* in 1981 further reveals that the confidentiality provisions were not intended to be absolute²⁵¹ and that a reasonableness standard should apply in determining the adequacy of each study’s confidentiality provisions.²⁵² HHS suggested in the same commentary that confidentiality provisions might be reasonable if they required the investigator to apply for a certificate of confidentiality, which is a legal mechanism that protects the investigator from making compulsory disclosures of study data.²⁵³

The Common Rule places the burden on the IRB to determine the adequacy of the investigator’s confidentiality protections and the adequacy of the statement in the informed consent documentation, if not waived, regarding the extent to which confidentiality of records identifying the subject will be maintained.²⁵⁴ For the IRB to make such a determination, the investigator needs to describe to the IRB the specific confidentiality policies and procedures that have been established for the study. In the functional neuroimaging context, relevant policies and procedures certainly could involve replacing names and other identifiers embedded in neuroimages or contained on record labels with codes; storing raw image data and related paper and

248. *Id.* § 46.117(c)(1).

249. *Id.*

250. See Jennifer Kulynych, *Legal and Ethical Issues in Neuroimaging Research: Human Subjects Protection, Medical Privacy, and the Public Communication of Research Results*, 50 BRAIN & COGNITION 345, 353 (2002).

251. Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects, 46 Fed. Reg. 8366, 8386 (Jan. 26, 1981) (“[I]t is inappropriate to require institutions to give assurances of privacy and confidentiality which they may not be able to honor in all circumstances.”) (codified as amended at 45 C.F.R. pt. 46).

252. *Id.* (“Confidentiality provisions should meet reasonable standards for protection of privacy and comply with applicable laws.”).

253. *Id.* (“Reasonable protection might in some instances include legal protection available upon application (such as the immunity from legal process of certain drug and alcohol abuse and mental health research subject data under [the Public Health Service Act]).”). See Part IV.D, *infra*, for a discussion of certificates of confidentiality.

254. Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects, 46 Fed. Reg. at 8383.

electronic research records securely during the research study; planning for the long-term storage and use of raw image data and related records; and ensuring that any neuroimages and related data sets and reports that are disclosed to neuroimaging databanks and other third parties are completely stripped of all identifiers, including any image elements that could be reconstructed into cranial-facial features. The IRB is required to review any such policies and procedures and determine their adequacy.²⁵⁵

Unfortunately, some scientists do not provide sufficient descriptions of their confidentiality provisions to enable the IRB to determine whether the provisions are adequate. Indeed, the OHRP found in October 2005 that IRBs frequently lack information to determine whether a particular research protocol has adequate confidentiality provisions.²⁵⁶ According to the OHRP, many IRBs only review minimal information, such as boilerplate informed consent language, regarding the establishment of confidentiality policies and procedures.²⁵⁷ The OHRP concluded that IRBs appear not to be systematically or rigorously considering confidentiality issues.²⁵⁸ In summary, the Common Rule establishes a framework for protecting the confidentiality of some, but not all, fMRI study data. How well particular scientists using fMRI—and IRBs reviewing fMRI studies—adhere to this framework is unclear.

The Common Rule also does not address the unique confidentiality concerns raised by neuroimaging data sharing requirements. The sharing of data is important to many areas of science, including astrophysics, proteomics, and genomics.²⁵⁹ GenBank, a genome database, is a specific example of how data sharing has been used to benefit science and society.²⁶⁰ Neuroscience also stands to benefit from data sharing. Experts estimated in 2001 that investigators were conducting approximately 1,500 new brain imaging studies each year, involving 10,000 human subjects and 100 terabytes of neuroimaging data, although published studies revealed only a small portion of the neuroimaging data actually collected.²⁶¹ Proponents of neuroimaging databanks believe that databanks make neuroimaging data more accessible for sharing, which facilitates the comparison of

255. *Id.* at 8383.

256. OFFICE HUM. RES. PROTS, DIV. OF COMPLIANCE OVERSIGHT, OHRP COMPLIANCE OVERSIGHT ACTIVITIES: SIGNIFICANT FINDINGS AND CONCERNS OF NONCOMPLIANCE 3 (2005).

257. *Id.* at 3, 10.

258. *Id.* at 3.

259. Governing Council of the Organization for Human Brain Mapping, *Neuroimaging Databases*, 292 SCI. 1673, 1673 (2001) [hereinafter Organization for Human Mapping].

260. John D. Van Horn & Michael S. Gazzaniga, *Databasing fMRI Studies—Towards a 'Discovery Science' of Brain Function*, 3 NATURE REV. NEUROSCIENCE 314, 314 (2002).

261. Organization for Human Brain Mapping, *supra* note 259, at 1673.

neuroimaging findings across laboratories, allows for better assessment of the reliability of methods and reproducibility of results, encourages meta-analyses that explore phenomena that are not apparent in individual data sets, and provides investigators who do not have access to neuroimaging facilities the opportunity to conduct research using existing data.²⁶²

To that end, the National Science Foundation funded²⁶³ the fMRI Data Center (fMRIDC),²⁶⁴ “a public repository of peer-reviewed fMRI studies and their underlying data.”²⁶⁵ In addition to the National Institutes of Health (NIH), which requires all investigators who submit applications seeking \$500,000 or more in direct costs in a single year to address data sharing in their applications,²⁶⁶ the *Journal of Cognitive Neuroscience* at one point required its authors to submit their complete fMRI study data to the fMRIDC as a condition of publication,²⁶⁷ 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.²⁶⁸ The issue is whether scientists jeopardize data confidentiality when they submit functional neuroimaging information to neuroimaging databanks in accordance with funding and publication requirements.

If scientists de-identify data before making databank submissions, the subjects’ confidentiality concerns should be minimized because the data cannot be traced back to the subjects. The Common Rule regards information as not individually identifiable if the information “cannot be linked to specific individuals by the investigator(s) either

262. Sylvain Faisan et al., *Unsupervised Learning and Mapping of Active Brain Functional MRI Signals Based on Hidden Semi-Markov Event Sequence Models*, 24 IEEE TRANSACTIONS ON MED. IMAGING 263, 263 (2005); Joan O’C. Hamilton, *Journey to the Center of the Mind: “Functional” MRI Is Yielding a Clearer Picture of What Thoughts Look Like*, BUS. WK., Apr. 19, 2004, at 78; Organization for Human Brain Mapping, *supra* note 259, at 1673.

263. See *fMRI Data Center*, 15 OBSERVER (Am. Psychol. Soc’y), Jan. 2002, at 1 (“Thanks to a substantial grant from the National Science Foundation, the fMRI Data Center opened its virtual doors in the autumn of 1999.”).

264. fMRI Data Center, General Information, <http://www.fmridc.org/aboutus/index.html?id=nsT7bmAj> (last visited June 22, 2007).

265. fMRI Data Center, Welcome to the fMRI Data Center, <http://www.fmridc.org/> (last visited June 22, 2007).

266. NAT’L INSTS. OF HEALTH, FINAL NIH STATEMENT ON SHARING RESEARCH DATA, Notice NOT-OD-030032 (2003), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

267. Elliott Marshall, *A Ruckus over Releasing Images of the Human Brain*, 289 SCI. 1458, 1458 (2000).

268. John D. Van Horn et al., *The Functional Magnetic Resonance Imaging Data Center (fMRIDC): The Challenges and Rewards of Large-Scale Databasing of Neuroimaging Studies*, 356 PHIL. TRANSACTIONS ROYAL SOC’Y B: BIOLOGICAL SCI. 1323, 1324-25 (2001); see Van Horn & Gazzaniga, *supra* note 260, at 318.

directly or indirectly through coding systems.”²⁶⁹ Scientists routinely strip neuroimaging data of direct identifiers, such as names and birth dates, to render the data not identifiable prior to data sharing.²⁷⁰ However, rendering data not identifiable is further complicated in the functional neuroimaging context because of the existence of computer software that is capable of generating images of a subject’s cranio-facial features from raw neuroimaging data.²⁷¹ Functional neuroimaging thus raises unique confidentiality issues relating to the possible inadvertent disclosure of subjects’ facial images. To ensure that individuals who later mine neuroimaging databanks cannot recreate subjects’ facial images, scientists must strip, scramble, or obscure image elements in scans and datasets that are submitted to databanks.²⁷²

The fMRIDC is aware of the unique confidentiality issues raised by the sharing of raw neuroimaging data and has established author guidelines designed to maintain the confidentiality of that data. The guidelines require authors to remove identifiers such as name, subject initials, social security number, and internal subject identification codes before data is submitted to the fMRIDC.²⁷³ If an author fails to remove one or more identifiers, the fMRIDC will upon receipt of the data remove the identifiers itself.²⁷⁴ To eliminate the possibility that high-resolution fMRI images can be reconstructed to reveal the contours of subjects’ faces, the fMRIDC also strips high-resolution images of any remaining facial features.²⁷⁵ Finally, the fMRIDC recommends that investigators include statements in their informed consent forms identifying the potential for anonymized data collected from study participants to be made publicly available through the fMRIDC.²⁷⁶ Confidentiality concerns associated with neuroimaging databanks, although potentially significant, will be realized only when an investigator does not de-identify information prior to databank disclosure and if the receiving databank has failed to establish and adhere to internal de-identification policies and procedures like those established by the fMRIDC.

269. DEP’T HEALTH & HUM. SERVS., OFFICE HUM. RES. PROTS, GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS 3 (2004).

270. *See id.* at 2-3.

271. Paul Root Wolpe, *Neuroethics*, in *ENCYCLOPEDIA OF BIOETHICS* 1897 (3ded., vol. 4, Stephen G. Post ed., 2004); Arthur W. Toga, *Neuroimage Databases: The Good, the Bad and the Ugly*, 3 *NATURE REV. NEUROSCIENCE* 302, 307 (2002).

272. *Id.* at 308; Kulynych, *supra* note 250, at 353-54.

273. fMRI Data Center, Privacy Guidelines for Authors: The Protection of Human Subjects’ Data, § I, <http://www.fmridc.org/submissions/privacyguidelines.html> (last visited June 22, 2007).

274. Van Horn & Gazzaniga, *supra* note 260, at 314.

275. *Id.*

276. fMRI Data Center, *supra* note 273, at § V.

B. The Privacy Rule

Enacted on August 21, 1996, the Health Insurance Portability and Accountability Act (HIPAA)²⁷⁷ was designed primarily to eliminate employees' unwillingness to change jobs due to fear that they would not qualify for health insurance at their new places of employment.²⁷⁸ A second purpose, added later during the legislative process, was administrative simplification, or the more efficient processing of health claims through standard electronic transactions.²⁷⁹ Anticipating public concern about the confidentiality implications of shared electronic health information, Congress included a provision in HIPAA directing the federal Department of Health and Human Services (HHS) to adopt health information privacy²⁸⁰ regulations if Congress failed to pass privacy legislation within three years of HIPAA's date of enactment.²⁸¹ When Congress missed its own deadline, HHS became responsible for adopting privacy regulations.²⁸² Today, HHS' Privacy Rule (Privacy Rule)²⁸³ is codified in the same title of the Code of Federal Regulations as is the Common Rule.²⁸⁴

The Privacy Rule only applies to covered entities, defined to include health care providers who transmit health information in electronic form in connection with certain standard transactions.²⁸⁵ Many, but not all, health care providers transmit health information in electronic form in connection with insurance claims and other standard transactions. The Privacy Rule thus will apply to many of the radiologists, neurologists, hospitals, and imaging centers that create and use functional neuroimages to assist with neurosurgery and other treatments and procedures in the clinical setting.

However, fMRI currently is being used more frequently in the research context as a tool for investigations in human cognitive neuroscience.²⁸⁶ The application of the Privacy Rule to scientists who use fMRI to test various research hypotheses is less straightforward. If an investigator does not provide health care or does not transmit

277. Health Insurance and Accountability Act of 1996 (HIPPA), Pub. L. No. 104-191, 110 Stat. 1936.

278. 42 U.S.C. § 300gg (2000) (providing increased insurance portability through limitations on preexisting condition exclusions). See generally Rothstein, *supra* note 243, at 154.

279. HIPPA §§ 261-62, 110 Stat. at 2021-31 (codified as amended at 42 U.S.C. § 1320(d) (2000)).

280. Although Congress directed HHS to adopt *privacy* regulations, the regulations as adopted actually address *confidentiality* because they regulate the use and disclosure of protected health information by covered health care providers, health plans, and health care clearinghouses, not the collection of protected health information by third parties.

281. HIPAA § 264(c).

282. *Id.*

283. 45 C.F.R. pt. 164 (2006).

284. *Id.* pt. 46.

285. *Id.* §§ 162.1101-.1802, 164.104(a).

286. Jezzard & Buxton, *supra* note 41, at 791.

health information in electronic form in connection with a standard transaction such as a claim for reimbursement, the Privacy Rule will not regulate the investigator's research activities. Many of the studies discussed in Part III simply investigated the neural correlates of a range of social behaviors and characteristics such as deception, consumer preferences, romantic and maternal attachment, ethical decision making, and intelligence. These research projects did not involve the provision to study volunteers of health care—such as medical treatment, surgical procedures, counseling, or drugs—or the electronic billing of insurance companies for such health care. The Privacy Rule thus does not apply to all of the scientists who are conducting fMRI studies. The Privacy Rule also does not apply to many of the other individuals and organizations reported to have an interest in the creation or use of functional neuroimaging information, including employers, life insurance companies, educational institutions, criminal justice officials, courts, litigants, and marketing companies.²⁸⁷

In addition, the Privacy Rule only regulates covered entities' use and disclosure of a certain class of information known as protected health information,²⁸⁸ which is generally defined as individually identifiable health information.²⁸⁹ Health information includes information that “[r]elates to the past, present, or future physical or mental health or condition of an individual . . . [as well as] the provision of health care to an individual.”²⁹⁰ For example, a structural MRI showing diffuse brain damage resulting from traumatic brain injury or stroke would constitute health information because the MRI would relate to the past and present physical health of the individual. An fMRI that is interpreted to reveal that an individual has schizophrenia or will develop Alzheimer's disease also would constitute health information because the interpretations would relate to the subject's current and future mental health.

But, what about fMRI scans that are taken for purposes of studying many of the social phenomena identified in Part III? For example, what if fMRI is used to study one-time deception that does not rise to the level of pathological lying (“I do not have the 5-of-clubs card”)? What about an fMRI scan that shows amygdala activity interpreted as unconscious social evaluation of a person who belongs to a different social or racial group? What about an fMRI scan 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 protected by the

287. See Rothstein, *supra* note 243, at 155.

288. 45 C.F.R. § 164.500(a) (2006).

289. See *id.* § 160.103.

290. *Id.*

Privacy Rule because they do not relate to the physical or mental health or condition of an individual.

Health information must be individually identifiable to be regulated by the Privacy Rule.²⁹¹ An fMRI scan would be considered individually identifiable if it contained either an embedded direct identifier or one on a label, such as a patient or subject's name or social security number.²⁹² As with the Common Rule, the question of whether raw neuroimaging data is inherently identifiable because of its ability to be reconstructed by computer software into cranial-facial feature images also exists under the Privacy Rule, especially because the Privacy Rule considers "[f]ull face photographic images," "comparable images," "and any other unique identifying characteristics" to be identifiers.²⁹³

Unlike the Common Rule, which provides little guidance regarding how scientists are supposed to maintain the confidentiality of study data, the Privacy Rule contains detailed provisions that attempt to balance individuals' confidentiality rights against various needs for protected health information. For example, the Privacy Rule permits covered entities to use and disclose protected health information without prior authorization for the activities of treatment, reimbursement, and health care operations, as well as twelve additional public policy activities.²⁹⁴ A brief review of some of these permitted uses and disclosures shows just how frequently the confidentiality of functional neuroimaging information is not required to be maintained.

Treatment is defined to include "the provision, coordination, [and] management of health care and related services."²⁹⁵ Again, the Privacy Rule permits covered entities to use and disclose protected health information for treatment activities without the prior permission of the subject of the information. The theory is that patients who consent to treatment impliedly consent to health care providers using their information as part of such treatment.

However, somewhat unique confidentiality concerns are raised in the clinical and research settings when fMRI reveals incidental findings.²⁹⁶ For example, what happens when an individual consents to research designed to test a hypothesis relating to the treatment of schizophrenia, but the covered scientist discovers through fMRI that

291. *See id.*

292. *Id.* § 164.514(b)(2)(A)-(R).

293. *Id.* § 164.514(b)(2)(Q)-(R).

294. *Id.* §§ 164.501, -.506(c)(1), -.508, -.512.

295. § 164.501.

296. Incidental findings have been defined "as observations of potential clinical significance unexpectedly discovered in healthy subjects or in patients recruited to brain imaging research studies and unrelated to the purpose or variables of the study." Judy Illes et al., *Incidental Findings in Brain Imaging Research*, 311 *SCI.* 783, 783 (2006).

the subject has an unrelated brain tumor? How can the scientist ensure that the individual obtains treatment for the brain tumor while maintaining confidentiality as is required by the Privacy Rule?

The ability of fMRI and other neuroimaging technologies to reveal incidental findings has drawn significant attention in the neuroethics literature.²⁹⁷ Several recent studies have analyzed the extent to which scientists have discovered arteriovenous malformations, brain tumors, developmental abnormalities, and other conditions in healthy controls who volunteer for neuroimaging research.²⁹⁸ A 2004 study designed in part to characterize the frequency and severity of incidental findings in fMRIs detected incidental findings in 47% of the 151 scans examined and classified 6.6% of the scans as requiring clinical follow-up.²⁹⁹ The authors of a second study published in 2004 found substantial variability in investigators' procedures for handling unanticipated findings.³⁰⁰ Of six consent forms reviewed by the authors during the second study, four did not contain any language specifically addressing unanticipated findings,³⁰¹ although one investigator whose procedures were reviewed did report unanticipated findings directly to the research subject's primary care provider according to provisions in the consent form explaining that such reporting would take place.³⁰²

How does the Privacy Rule regulate such referrals and reports? If a covered scientist makes an incidental finding, is the scientist legally and ethically permitted or required to send the scan to the subject's primary care provider or a radiologist for review? Because the Privacy Rule broadly defines treatment to include "the coordination or management of health care by a health care provider with a third party," as well as consultations and referrals,³⁰³ a covered scientist is legally permitted by the Privacy Rule to disclose an abnormal fMRI

297. See, e.g., *id.*; *Proceedings of Managing Incidental Findings in Human Subjects Research: From Imaging to Genomics Conference*, Univ. of Minn., Mar. 1, 2007; Nat'l Inst. Neurological Disorders & Stroke, *Detection and Disclosure of Incidental Findings in Neuroimaging Research*, Jan. 6-7, 2005, http://www.ninds.nih.gov/news_and_events/proceedings/ifexecsummary.htm; Judy Illes et al., *Discovery and Disclosure of Incidental Findings in Neuroimaging Research*, 20 J. MAGNETIC RESONANCE IMAGING 743, 743 (2004) [hereinafter, Illes et al., *Discovery and Disclosure*]; J. Illes et al., *Ethical Consideration of Incidental Findings on Adult Brain MRI in Research*, 62 NEUROLOGY 888, 888 (2004) [hereinafter Illes et al., *Ethical Consideration*]; Judy Illes et al., *Ethical and Practical Considerations in Managing Incidental Findings in Functional Magnetic Resonance Imaging*, 50 BRAIN & COGNITION 358, 358 (2002); Gregory L. Katzman et al., *Incidental Findings on Brain Magnetic Resonance Imaging from 1000 Asymptomatic Volunteers*, 281 J. AM. MED. ASS'N 36, 36 (1999).

298. See *supra* note 296.

299. Illes et al., *Ethical Consideration*, *supra* note 297, at 889.

300. Illes et al., *Discovery and Disclosure*, *supra* note 297, at 745.

301. *Id.*

302. *Id.*

303. 45 C.F.R. § 164.501 (2006).

scan to another health care provider, including a primary care provider, neurosurgeon, or other physician, for treatment, even without the prior written authorization of the research subject.³⁰⁴ Although the scientist arguably has an ethical obligation to notify the subject of the incidental finding, as discussed in more detail in Part VI, the Privacy Rule does not legally require a covered scientist to obtain follow-up or treatment for the subject because the Privacy Rule does not contain substantive reporting or treatment mandates.

Treatment is just one of the activities for which covered providers and scientists are permitted to use and disclose protected health information without the prior authorization of the patient or research subject. The Privacy Rule also permits covered entities to use and disclose protected health information for twelve enumerated public policy activities, which are also referred to as “exceptions” to the general authorization requirement.³⁰⁵ Because these exceptions provide examples of situations in which the confidentiality of fMRI records are not required to be maintained, a brief review of their provisions is worthwhile.

The first exception that is potentially relevant in the functional neuroimaging context relates to uses and disclosures of protected health information that are required by law. The Privacy Rule expressly permits covered entities to use or disclose protected health information without prior authorization if the “use or disclosure is required by law and . . . complies with and is limited to the relevant requirements of such law.”³⁰⁶ For example, if a covered entity discovers during an fMRI scan a condition that state law requires to be reported to a local health department or similar agency, then the Privacy Rule permits, but does not require, the entity to make the information disclosure. A specific example might involve uncontrolled sleepiness or seizures associated with sleep apnea, narcolepsy, epilepsy, or other neurological disorders, which some states require diagnosing physicians to report to the appropriate state agency.³⁰⁷

The Privacy Rule permits disclosures required by another law if the disclosure “complies with and is limited to the relevant requirements of such law.”³⁰⁸ If the information required by the law is a one-

304. *Id.* § 164.506(c)(2).

305. *Id.* § 164.512(a)(1).

306. *Id.*

307. *See, e.g.*, Gordon H. Campbell, *Driving and Neurological Disease* (Feb. 27, 2007), <http://www.emedicine.com/neuro/topic594.htm> (noting that some state authorities mandate physicians to report individuals with certain diagnoses, particularly epilepsy, to a relevant state agency); WISC. ADM. CODE [Transp.] § 112.10 (2005) (regulating the issuance of motor vehicle operator licenses to persons who have certain medical conditions); MED. REVIEW UNIT, WIS. DEP'T TRANSP. MEDICAL EXAMINATION REPORT 1, 2 (2006), *available at* <http://www.dot.wisconsin.gov/drivers/forms/mv3644.pdf>.

308. 45 C.F.R. § 164.512(a)(1) (2006).

word diagnosis, the Privacy Rule thus would prohibit the disclosure of an underlying fMRI scan. However, many state laws require the disclosure of more than one-word diagnoses.³⁰⁹ A Wisconsin reporting form asks longer questions such as, “Does this person’s neurological condition involve movement disorder? If yes, please explain.”³¹⁰ The Wisconsin reporting form does request EEG (although not yet fMRI) results.³¹¹

A second exception relates to uses and disclosures of protected health information for public health activities. Among other activities, the Privacy Rule permits covered entities to disclose protected health information to a public health authority “for the purpose of preventing or controlling disease, injury, or disability,” and to make reports regarding the quality, safety, or efficacy of a Food and Drug Administration regulated product or activity.³¹² This provision expressly permits covered entities to report diseases, injuries, vital events, and the conduct of public health surveillance, public health investigations, and public health interventions to public health authorities such as the federal Center for Disease Control and Prevention and state health departments.³¹³ Among other things, this provision would allow a covered entity to disclose a disease or injury detected by fMRI to a local public health authority without prior authorization of the individual who is the subject of the image if the purpose of the disclosure is to prevent or control disease, injury, or disability.

A third exception relates to uses and disclosures of protected health information for certain health oversight activities. Under this provision, covered entities are permitted to disclose protected health information to health oversight agencies—such as HHS, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and the OHRP—for oversight activities authorized by law.³¹⁴ Oversight activities are defined to include “audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of . . . [t]he health care system.”³¹⁵ For example, if the OHRP conducted an investigation of alleged research misconduct by a number of investigators at a particular institution, the investigators would be permitted to disclose their research records, including fMRI study records, in response to a demand for such records by the OHRP.

309. MEDICAL EXAMINATION REPORT, *supra* note 307, at 2.

310. *Id.*

311. *Id.*

312. 45 C.F.R. § 164.512(b).

313. *Id.*

314. *Id.* § 164.512(d)(1).

315. *Id.*

A fourth exception relates to the disclosure of protected health information for judicial and administrative proceedings.³¹⁶ This provision permits covered entities to disclose protected health information in the course of a judicial or administrative proceeding “[i]n response to an order of a court or administrative tribunal” if the covered entity “discloses only the protected health information expressly authorized by such order.”³¹⁷ If a court orders a covered entity to disclose an fMRI scan, the Privacy Rule permits the entity to do so. This provision also permits covered health care providers and scientists to disclose protected health information “[i]n response to a subpoena, discovery request, or other lawful process, that is not accompanied by” a court order if the covered provider or scientist receives certain assurances specified in the Privacy Rule from the party seeking the information.³¹⁸ Even without a court order, then, a covered entity is permitted to disclose an fMRI scan or related report in the litigation context if the entity obtains the specified assurances from the party seeking the information.

A fifth exception relates to disclosures of protected health information for law enforcement purposes. This provision permits covered entities providers and scientists to disclose protected health information to law enforcement officials for certain law enforcement purposes.³¹⁹ One such purpose involves “a law enforcement official’s request for . . . information about an individual who is or is suspected to be a victim of a crime.”³²⁰ In the structural neuroimaging context, a relevant example might involve a radiologist who interpreted a neuroimage as revealing shaken-baby syndrome.³²¹ In the functional neuroimaging context, a futuristic, speculative example might involve a scientist who interpreted an fMRI as revealing that certain areas of a rape victim’s brain were activated when she was shown an image of a particular criminal or the scene of the rape. The Privacy Rule would permit the covered radiologist or scientist to disclose information needed by the law enforcement officer to enforce applicable laws relating to child abuse and rape, respectively.

A sixth exception relates to research activities. The Privacy Rule permits covered entities to use and disclose protected health information without prior authorization for four types of research activities.³²² These include retrospective research using the information of

316. *Id.* § 164.512(e)(1)(i).

317. *Id.*

318. *Id.* § 164.512(e)(1)(ii)-(iv).

319. *Id.* § 164.512(f).

320. *Id.* § 164.512(f)(3).

321. *See, e.g.*, Committee on Child Abuse and Neglect, American Academy of Pediatrics, *Shaken Baby Syndrome: Rotational Cranial Injuries—Technical Report*, 108 PEDIATRICS 206, 208 (2001).

322. 45 C.F.R. § 164.512(i)(1).

decedents,³²³ certain reviews of information that are preparatory to research,³²⁴ situations in which an IRB or privacy board has approved the waiver of the otherwise required authorization to use or disclose information,³²⁵ and situations in which the researcher will only be using a limited data set of information and the researcher has executed a data use agreement with the data holder.³²⁶

An example of the second type of research activity might involve an investigator who would like to review a class of protected health information, such as “all fMRI scans and records of patients who have had brain surgery in the last five years,” to determine whether a sufficient number of patients exist to test a particular hypothesis relating to the assistance provided by fMRI in planning surgical routes or assessing surgical risk. The Privacy Rule would permit a workforce member of the health care facility that maintains the fMRI scans and related records to contact and recruit the patients without prior IRB approval or patient authorization once the investigator has determined that her hypothesis is testable and makes certain representations regarding her use of the fMRI scans and related records.

A seventh exception relates to uses and disclosures of protected health information that are necessary to avert serious threats to health or safety.³²⁷ The Privacy Rule expressly permits a covered entity to

use or disclose protected health information, if the covered entity in good faith, believes the use or disclosure . . . [i]s necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public . . . and [i]s to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.³²⁸

To the extent fMRI technology advances this far, this provision would permit a covered provider or scientist who had interpreted a particular patient’s fMRI to reveal imminent murderous tendencies to reveal that information to law enforcement authorities or the murder target.

An eighth exception relates to national security and intelligence activities. One portion of this provision expressly permits a covered entity to “disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Se-

323. *Id.* § 164.512(i)(1)(iii)

324. *Id.* § 164.512(i)(1)(ii).

325. *Id.* § 164.512(i)(1)(i).

326. *Id.* § 164.514(e)(1)-(4).

327. *Id.* § 165.514(j).

328. *Id.* § 164.512(j)(1)(i).

curity Act.”³²⁹ To the extent fMRI technology advances this far, this provision would permit a covered entity that interprets an fMRI to reveal an individual’s knowledge of a terrorist activity to disclose relevant information to authorized federal officials without the prior permission of the individual.

In addition to these eight exceptions, the Privacy Rule expressly allows health care providers to condition the provision of a neuroimaging examination on the patient’s execution of an authorization form allowing the provider to disclose the fMRI test results to an employer if the purpose of the examination was to create information for use by the employer.³³⁰ The Privacy Rule also permits health insurance companies to require an individual to sign an authorization form for the disclosure of her functional neuroimaging information if the individual would like to be considered for enrollment in the health plan or the information is needed for underwriting or risk-rating determinations or to determine eligibility for benefits.³³¹ The Privacy Rule thus does not prohibit a covered health care provider from disclosing functional neuroimaging information pursuant to an individual’s written authorization that is compelled by an employer or health insurance company.

In summary, the Privacy Rule only regulates covered health care providers when they are using or disclosing protected health information. The Privacy Rule does not regulate all of the scientists who are conducting fMRI studies or all of the other parties that are reported to have an interest in the creation or obtaining of functional neuroimaging information. In addition, the Privacy Rule expressly permits covered entities to use and disclose functional neuroimaging information for treatment, reimbursement, health care operations, and twelve public policy activities, at least eight of which are potentially applicable in the functional neuroimaging context. Finally, the Privacy Rule expressly permits employers and health insurance companies to condition treatment and health plan enrollment on an individual’s execution of an authorization form for the release of her functional neuroimaging information. Like the Common Rule, then, the Privacy Rule also establishes incomplete confidentiality protections for functional neuroimaging information.

C. State Law

In addition to federal rules, such as the Common Rule and the Privacy Rule, many states have medical practice acts, hospital licensing laws, imaging center licensing laws, and other similar statutes

329. *Id.* § 164.512(k)(2).

330. *Id.* § 164.508(b)(4)(iii).

331. *Id.* § 164.508(b)(4)(ii).

and regulations that require certain individuals and institutions to maintain the confidentiality of health information in their possession.³³² How a particular state law applies to the functional neuroimaging context depends on whether the law's protections extend to scientists who do not provide health care as part of their research and whether the law protects social information in addition to medical records and other health-related information.³³³ Like the Privacy Rule, many state health information confidentiality laws permit the use and disclosure of health information without prior authorization for a range of activities.³³⁴ Many state laws also fail to prohibit organizations such as employers and health insurance companies from requiring individuals to sign an authorization form for the release of their functional neuroimaging information.³³⁵ Like the Common Rule and the Privacy Rule, then, state health information confidentiality laws also provide incomplete protections for functional neuroimaging information.

D. *Certificates of Confidentiality*

Congress initially provided for certificates of confidentiality in 1970 as part of the national war on drugs.³³⁶ The certificates were designed to assure research subjects who participated in drug addiction and abuse studies that the information they shared with researchers would remain completely confidential.³³⁷ Congress amended the Public Health Service Act in 1988 to authorize agencies within HHS to issue certificates of confidentiality to investigators engaged in all biomedical, behavioral, clinical, mental health, and other research studies, not just research relating to drug addiction and abuse.³³⁸ Today, certificates of confidentiality allow investigators to withhold

332. With some exceptions, the Privacy Rule preempts state laws that provide less stringent confidentiality protections, although more stringent state laws may survive preemption. 45 C.F.R. § 160.203(b).

333. Although beyond the scope of this Article, a fifty-state survey of health information confidentiality laws and regulations has been attempted by the Health Privacy Project. See JOY PRITTS ET AL., *THE STATE OF HEALTH PRIVACY: AN UNEVEN TERRAIN (A COMPREHENSIVE SURVEY OF STATE HEALTH STATUTES)* (1999).

334. See, e.g., MINN. STAT. § 144.335(3a)(b) (2005) (permitting the release of health records for a number of public policy activities); TEX. OCC. CODE ANN. § 159.003 (Vernon 2005) (listing a number of exceptions to confidentiality in court or administrative proceedings); id. § 159.004 (2000) (listing a number of exceptions to confidentiality in other situations).

335. See, e.g., MINN. STAT. § 144.335(3c) (2006) (permitting health care providers to release health records as directed as part of an independent medical examination to the third party who requested or paid for the examination).

336. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, §50d, 84 Stat. 1236, 1271 (codified at 21 U.S.C. § 872(c)).

337. Janlori Goldman & Angela Choy, *Privacy and Confidentiality in Health Research*, in 2 NAT'L BIOETHICS ADVISORY COMM'N, *ETHICAL & POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS C-1, C-18* (2001).

338. 42 U.S.C. § 241(d) (2002).

names and other identifiable data about research participants that otherwise may be summoned “under Federal, State, or local civil, criminal, administrative, legislative, or other proceedings.”³³⁹ The NIH has taken the position that certificates of confidentiality, which have been available for non-federally funded research since 1993,³⁴⁰ supersede contrary state and federal laws, and case law has upheld certificates of confidentiality against otherwise compulsory disclosures.³⁴¹

Certificates of confidentiality can provide additional confidentiality protections in the functional neuroimaging context, but investigators must be knowledgeable about their application. A certificate of confidentiality can only be requested for a research project that involves the gathering of sensitive information.³⁴² Information is sensitive if its disclosure “could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.”³⁴³ Examples of information the NIH has classified as sensitive include genetic information; information relating to the psychological well-being of human subjects; information on subjects’ sexual attitudes, preferences, or practices; and data on substance abuse or illegal conduct.³⁴⁴ As discussed in Part III, fMRI has the potential to reveal sensitive information about individuals, including their mental health, sexual preferences, and addictive tendencies, and speculation exists that employers, insurance companies, and others may attempt to obtain this information. Research involving fMRI thus may be ripe for the additional confidentiality protections provided by certificates of confidentiality.

Although certificates of confidentiality protect investigators from making otherwise compulsory disclosures, they do not prohibit investigators from making noncompulsory, unauthorized disclosures.³⁴⁵

339. *Id.*

340. Joan E. Seiber, *Privacy and Confidentiality: As Related to Human Research in Social and Behavioral Science*, in 2 NAT’L BIOETHICS ADVISORY COMM’N, ETHICAL & POL’Y ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS N-1, N-18 (2001).

341. *People v. Newman*, 298 N.E.2d 651, 654, 657 (N.Y. 1973) (holding that federal certificate of confidentiality provisions, not New York physician-patient privilege, prohibited disclosure of individually identifiable information regarding individuals undergoing methadone treatment).

342. OFFICE EXTRAMURAL RES., NAT’L INSTS. HEALTH, CERTIFICATES OF CONFIDENTIALITY: BACKGROUND INFORMATION (2006), available at <http://grants.nih.gov/grants/policy/coc/background.htm> [hereinafter CERTIFICATES BACKGROUND].

343. *Id.*; OFFICE EXTRAMURAL RES., NAT’L INSTS. HEALTH, FREQUENTLY ASKED QUESTIONS ON CERTIFICATES OF CONFIDENTIALITY (Mar. 15, 2002), available at <http://grants.nih.gov/grants/policy/coc/faqs.htm> [hereinafter CERTIFICATES QUESTIONS].

344. *Id.*

345. See, e.g., Mark A. Rothstein & Meghan A. Talbott, *Compelled Authorizations for Disclosure of Health Records: Magnitude and Implications*, 7 AM. J. BIOETHICS 38 (2007) (examining the scope of disclosures permitted pursuant to compelled authorizations); Seiber, *supra* note 340, at N-18.

Certificates of confidentiality thus are helpful when an investigator desires to maintain the confidentiality of her subjects' data; however, the certificates are not especially helpful when an investigator intentionally or unknowingly breaches confidentiality in a situation not involving compulsion. Certificates of confidentiality, which are research-project - and not investigator - or institution - specific, also must be requested by the investigator from the applicable agency prior to the beginning of each research project, a requirement about which many investigators do not know or lack the diligence to meet.³⁴⁶ Because certificates of confidentiality can fill some of the confidentiality gaps left by the Common Rule, the Privacy Rule, and state law,³⁴⁷ investigators engaged in functional neuroimaging research should be encouraged to apply for a certificate prior to the commencement of each research project. IRBs also should be educated regarding the protections provided by certificates of confidentiality and regarding their application process.³⁴⁸

In summary, confidentiality provisions in the Common Rule, the Privacy Rule, state law, and the certificate of confidentiality provisions do not protect all functional neuroimaging information. First, these confidentiality provisions do not regulate all of the individuals and organizations reported to have an interest in the creation or use of functional neuroimaging information. Second, the first three confidentiality provisions permit the disclosure of functional neuroimaging information to several categories of third parties for various public policy activities the benefit of which may not outweigh the unique confidentiality interests of research subjects and patients in their functional neuroimaging information. Third, and perhaps most importantly, the first three provisions do not prevent third parties such as employers and insurance companies from requiring individuals to authorize disclosures of their functional neuroimaging information for use in fitness-for-duty, insurance coverage, and other decisions.

V. PRIVACY

Part IV argued that existing principles of confidentiality incompletely protect functional neuroimaging information in part because individuals can be forced to authorize disclosures of their functional neuroimaging information. This Part builds on this point by examining the privacy implications of advances of functional neuroimaging, including the interest of individuals in avoiding the unwanted collec-

346. *Id.*

347. *See, e.g.*, CERTIFICATES QUESTIONS, *supra* note 343 (“[R]esearchers . . . may obtain Certificates of Confidentiality to protect them from being forced to disclose information that would have to be disclosed under the Privacy Rule.”).

348. *See generally id.* (providing information about the protection and application process of Certificates of Confidentiality).

tion of their functional neuroimaging information in the clinical, research, employment, and insurance contexts.³⁴⁹ Privacy losses in these contexts are concerning because they can result in psychological harm, including worry, irritation, fear, embarrassment, and self-doubt; social harm, including stigmatization; economic harm, including employment discrimination, loss of insurance benefits and inability to obtain insurance coverage; and legal harm, including arrest or conviction of a crime.³⁵⁰

A. *The Clinical and Research Contexts*

Functional MRI raises both traditional and unique privacy concerns in the clinical and research contexts. For example, if a research subject consents to a neuromarketing study the stated purpose of

349. Of course, fMRI also raises privacy concerns in the education, evidence, government, criminal justice, and other commercial contexts. These concerns are introduced elsewhere. *See, e.g.*, Kimberly Sheridan et al., *Neuroethics in Education*, in *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* 265, 265-75 (Judy Illes ed., 2006) (education); Mark Pettit, Jr., *fMRI and BF Meet FRE: Brain Imaging and the Federal Rules of Evidence*, 33 *AM. J.L. & MED.* (forthcoming (2007) (evidence); Charles N.W. Keckler, *Cross-Examining the Brain: A Legal Analysis of Neural Imaging for Credibility Impeachment*, 57 *HASTINGS L.J.* 509, 537-56 (2006) (evidence); Stephen J. Morse, *Moral and Legal Responsibility and the New Neuroscience*, in *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* 33, 47-49 (Judy Illes ed., 2006) (evidence); Stephen J. Morse, *New Neuroscience, Old Problems*, in *NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE* 157, 195-98 (Brent Garland ed., 2004) (evidence). In the government and criminal justice contexts, the United States Department of Defense and the Central Intelligence Agency reportedly have invested millions of dollars in neuroimaging technologies that might be used in law enforcement and intelligence, with a particular emphasis on brain scans that might be used to identify terrorists. *See supra* notes 117-18. The Pentagon's Defense Advanced Research Projects Agency (DARPA) already supports research at Lockheed Martin and Rutgers University relating to remote brain prints. *See supra* note 119. DARPA also has funded research by an Oregon organization relating to the creation of brain sensors that would detect, transmit, and reconstruct certain brain signals. *See* Greely, *supra* note 237, at 148; Farah & Wolpe, *supra* note 16, at 38. One issue is whether a government-imposed fMRI violates an individual's privacy of thought under the First Amendment. *See, e.g.*, Richard Glen Boire, *On Cognitive Liberty (Part I)*, 1 *J. COGNITIVE LIBERTIES* 7, 7 (2000). A second issue is whether a government-imposed fMRI constitutes a search and seizure of the brain for purposes of the Fourth Amendment. *See, e.g.*, Richard G. Boire, *Searching the Brain: The Fourth Amendment Implications of Brain-Based Deception Detection Devices*, *AM. J. BIOETHICS*, Mar.-Apr. 2005, at 62, 62-63. A third issue is whether the results of an fMRI constitute testimonial evidence protected by the Fifth Amendment's privilege against self-incrimination or physical evidence, which is not privileged under *Schmerber v. California*, 384 U.S. 757, 759-65 (1966) (blood-alcohol test result not privileged), and progeny or whether the testimony versus physical evidence approach is all wrong. *See, e.g.*, Sarah E. Stoller & Paul Root Wolpe, *Emerging Neurotechnologies for Lie Detection and the Fifth Amendment*, 33 *AM. J.L. & MED.* (forthcoming 2007); Sean Kevin Thompson, *A Brave New World of Interrogation Jurisprudence?*, 33 *AM. J.L. & MED.* (forthcoming 2007) (arguing for a "shocks the conscience" Fifth Amendment approach).

350. *See* Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 31, 32 (Mark A. Rothstein ed., 1997); Mark A. Rothstein, *Genetic Secrets: A Policy Framework*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 451,452 (Mark A. Rothstein ed., 1997); *CERTIFICATES QUESTIONS*, *supra* note 343.

which is to test whether a particular automobile design activates the part of the brain known to be related to attention and interest, but the investigator also discovers that the subject has a brain tumor or interprets the subject's fMRI scan as revealing that the subject has a particular mental health condition, the subject arguably had a privacy interest in avoiding the unwanted intrusions into her physical and mental health conditions. After all, she only consented to have her brain studied to determine whether she found the automobile appealing.

Privacy concerns vary by type and context, and procedures designed to protect the privacy of patients and research subjects in one setting may not be sufficient in the functional neuroimaging setting. Factors such as culture, ethnicity, age, socioeconomic status, gender, locale, the nature and context of the research, and the social and political environment affect individuals' sense of privacy differently, and providers and scientists cannot assume that each patient or research subject will regard the same things as private.³⁵¹ As an illustration, some patients and research subjects freely share their sexual experiences in response to queries about such experiences, while a request for information regarding sexual practices may be offensive to others.³⁵² Respecting privacy in the functional neuroimaging context thus requires more than obtaining consent to access neuroimaging information.³⁵³ To respect privacy, health care providers and investigators must tailor privacy protections to particular treatments and research studies. Providers and investigators must explain the privacy implications of their research, including the fact that fMRI can reveal incidental findings, and provide the opportunity for patients and research subjects to control, limit, or refuse access to their neuroimaging information, as appropriate.³⁵⁴

Privacy guidelines offered by other disciplines, including anthropology, psychology, and oral history, can be instructive.³⁵⁵ The *Code of Ethics* of the American Anthropological Association (AAA) recites what by now appears to be a basic privacy right: "Anthropological researchers must do everything in their power to ensure that their research does not harm the . . . privacy of the people with whom they work, conduct research, or perform other professional activities."³⁵⁶ Given the different types of anthropological research and the difficulty of establishing a one-size-fits-all solution to privacy, the AAA recommends that anthropological researchers carefully and respect-

351. NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL & POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 105, 105 (vol. II, 2001) [hereinafter NBAC VOL. II].

352. *Id.*

353. *Id.*; see Kennedy, *supra* note 58, at 19.

354. NBAC VOL. I, *supra* note 351, at 105-06.

355. *Id.* at 106.

356. AM. ANTHROPOLOGICAL ASS'N, CODE OF ETHICS § III(A)(2) (1998).

fully negotiate the limits of each research relationship.³⁵⁷ A similar negotiation approach could be applied in the clinical and research contexts in which fMRI is used.

For example, providers and scientists could clarify, as part of the informed consent conversation, the possibility of the discovery of unanticipated information as well as the different classes of information that have been discovered in the past, including arteriovenous malformations, brain tumors and developmental abnormalities. Other types of health information, social information, and thought processes that could be revealed by fMRI could be described as accurately as then possible. Two more possibilities could also be disclosed to the subject: the possibility of an inaccurate interpretation and the possibility that such interpretation could mislead third parties who rely on the interpretation to make decisions.³⁵⁸

In the volunteer research context, the individual then could be asked to consider whether she would be comfortable authorizing access to this information as part of the research protocol or whether she would prefer to keep these pieces of information to herself, in which case she could elect not to participate in the research. In the treatment context, the individual and the provider could negotiate a process to be followed in the event of an unanticipated finding. Although these procedures will not eliminate the discovery of incidental findings, they do give individuals more control over others' access to their neuroimaging information and may lessen the chance that a provider or investigator will intrude on a particular individual's sense of neurological privacy.

In the event of a neurological privacy breach, the common law of torts is one source of remedies. For example, the intrusion tort imposes liability on "[o]ne who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns . . . if the intrusion would be highly offensive to a reasonable person."³⁵⁹ The first element, an intentional physical or other intrusion, is frequently proved by the defendant's "physical intrusion into a place in which the plaintiff has secluded" herself, such as when the defendant forces his way into the plaintiff's hotel room or insists on entering the plaintiff's home over her objections.³⁶⁰ The element also may be proved by nonphysical intrusions, such as when the defendant uses his senses, with or without mechanical aids, to oversee or overhear the plaintiff's private affairs or when the defendant looks into the plaintiff's upstairs windows with binoculars, taps her tele-

357. *Id.* § III(A)(5).

358. *See Kennedy, supra* note 58, at 19.

359. RESTATEMENT (SECOND) OF TORTS § 652B (1977).

360. *Id.* § 652B cmt. b.

phone wires, or takes an unauthorized photograph of the plaintiff while she is in the “Fun-House.”³⁶¹

The intentional intrusion element could be proved in several ways in the functional neuroimaging context. An investigator could intentionally intrude on a research subject by making an unauthorized study of the subject’s personality or mental health when the subject had limited her consent to a brain scan the purpose of which was to study speech or language functions. If fMRI ever developed to the point where individuals’ brains could be scanned without their knowledge or authorization, the unauthorized scans also could constitute nonphysical intentional intrusions. Arguably any situation in which an individual is required to submit to functional magnetic resonance imaging over her objection could implicate the intentional intrusion element.

The second element of the intrusion tort requires the intrusion to be upon the solitude, seclusion, private affairs, or concerns of another.³⁶² Stated another way, a defendant will be subject to liability for intrusion “only when he has intruded into a private place, or has otherwise invaded a private seclusion that the plaintiff has thrown about [her] person or affairs.”³⁶³ A defendant generally will not be subject to intrusion liability if she simply examines a public record concerning the plaintiff or if she photographs the plaintiff while she is walking down a public street, because these activities are open to the public eye.³⁶⁴ Even in a public place, however, the tort will protect some matters about the plaintiff, “such as [her] underwear or lack of it, that are not exhibited to the public gaze,” if there is an intrusion into such a matter.³⁶⁵ Thoughts, feelings, and other mental processes that are studied by fMRI arguably constitute “private affairs or concerns” for purposes of the second element of the intrusion tort.

The final element of the tort requires the intrusion to be highly offensive to a reasonable person.³⁶⁶ Case law interpreting this element requires the plaintiff to prove that the intrusion was outrageous or that the intrusion would have caused “mental suffering, shame or humiliation to a person of ordinary sensibilities.”³⁶⁷ Although a structural MRI showing that an individual has a perfectly symmetrical skull might not be considered sufficiently outrageous, a functional MRI that is interpreted to reveal a “defect” in character or an “immoral” decision making process might be considered shameful or humiliating to a reasonable person.

361. *Id.* § 652B cmt. c, illus. 7.

362. *Id.* § 652B.

363. *Id.* § 652B cmt. c.

364. *Id.*

365. *Id.*

366. *Id.* § 652B cmt. d.

367. *Froelich v. Werbin*, 548 P.2d 482, 485 (Kan. 1976).

Whether an fMRI will constitute an intrusion will depend on several factors, including the purpose of the fMRI, whether the patient voluntarily submitted to the fMRI, and the information that is obtained as a result of the scan. An unauthorized fMRI would seem to implicate the tort more frequently than an authorized fMRI; however, an authorized research fMRI that exceeds the scope of the subject's consent also could constitute an intrusion.

A second privacy tort, appropriation, has limited although possible application in the functional neuroimaging context. The appropriation tort creates liability for [“o]ne who appropriates to his own use or benefit the name or likeness of another.”³⁶⁸ The classic appropriation case involves a defendant who makes an unauthorized use of an attractive plaintiff's image to advertise the defendant's business or product or for some similar commercial purpose (although not all jurisdictions require the defendant to commercially benefit from the use of the plaintiff's name or likeness).³⁶⁹

Recent scholarship suggests a role for the appropriation tort³⁷⁰ in cases such as *Moore v. Regents of the University of California*.³⁷¹ In *Moore*, the California Supreme Court decided in 1990 that plaintiff John Moore “had no property rights in the valuable pharmaceutical products that medical professionals had derived from Moore's spleen cells, after they had been removed as part of his treatment for leukemia.”³⁷² In so doing, the California Supreme Court overruled a lower court ruling finding that Moore had an appropriation cause of action “based on the commodification of an aspect of his body, his DNA, that was so intimately bound up with his identity as to be analogous to his name or image.”³⁷³ Recent scholarship considers how the Supreme Court could have applied the appropriation tort to inform and guide the legal management of Moore's DNA as well as other cases involving genetic information and other “information regarded as intimately bound up with a subject's identity.”³⁷⁴

Along these lines, the appropriation tort also might be used to inform and guide the legal management of neuroimaging information in certain limited situations. If a physician or investigator makes a neuroscientific discovery as a result of an fMRI of a particular individual's brain and benefits—commercially or otherwise—from the discovery, the patient or research subject could attempt to use the privacy tort of appropriation to the extent she did not license the par-

368. RESTATEMENT (SECOND) OF TORTS § 652C (1977).

369. See, e.g., *id.* § 652c cmt. b, illus. 1.

370. Jonathan Kahn, *Biotechnology and the Legal Constitution of the Self: Managing Identity in Science, the Market, and Society*, 51 HASTINGS L.J. 909, 909 (2000).

371. 793 F.2d 479 (Cal. 1990).

372. *Id.* at 480.

373. Kahn, *supra* note 370, at 909.

374. *Id.* at 911.

ticular benefit. To prevail, the patient or research subject would have to analogize her neurological identity to identity as typically represented by names or photographs and then argue that the provider or investigator benefited from the unauthorized appropriation of such neurological identity.

B. *The Employment Context*

There has been considerable speculation that employers will want to use fMRI to probe the minds of job applicants and current employees to determine whether to hire or maintain them.³⁷⁵ One company currently is marketing its brain scanning services directly to employers, and, at \$30 per minute, the scans may not be prohibitively expensive for all employers, especially those who hire well-paid professional or executive personnel.³⁷⁶ The issue is whether fMRI violates applicants and employees' interest in avoiding unwanted neurological intrusions.

One potential source of privacy rights for employees and job applicants is the Federal Americans with Disabilities Act (ADA).³⁷⁷ Title I of the ADA prohibits certain employers from discriminating on the basis of disability against qualified individuals with disabilities.³⁷⁸ As one way of preventing disability discrimination, Title I regulates covered employers' use of "qualification standards, employment tests or other selection criteria that screen out or tend to screen out" individuals with disabilities on the basis of such disabilities (the screening provisions).³⁷⁹ 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."³⁸⁰ EEOC regulations also clarify, however, that the following do not

375. Kenneth R. Foster et al., *Bioethics & the Brain*, IEEE SPECTRUM, June 2003, at 34 (describing a hypothetical scenario in which an airline fires a pilot after determining from an fMRI examination that the pilot "might develop schizophrenia, and had a surprising familiarity with assault rifles"); Ronald M. Green, *Spy Versus Spy*, AM. J. BIOETHICS, Mar.-Apr. 2005, at 53, 54 (speculating that employers might use fMRI for "pre-employment and employment-related testing for sensitive positions, or for informal investigative purposes"); Moreno, *supra* note 137, at 152 (speculating that employers will use fMRI to recruit applicants who experience more or less pleasure from social cooperation, depending on the requirements of the job); *The Ethics of Brain Science*, *supra* note 14 (speculating that job-recruiting agencies will prescreen job candidates using fMRI).

376. No Lie MRI, *supra* note 122; E-mails from Joel Huzzeniga, CEO, No Lie MRI, to author (May 17, 2006, 05:56:00 CST; May 23, 2006, 12:36:00 CST) (on file with author).

377. Americans with Disabilities Act (ADA) of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified as amended at scattered sections of 29 U.S.C., 42 U.S.C., & 47 U.S.C.).

378. ADA §§ 101-08, 104 Stat. at 330-37 (codified as amended at 42 U.S.C. §§ 12111-17).

379. 42 U.S.C. § 12112(b)(6) (2000); *see also* 29 C.F.R. § 1630.10 (2006).

380. 29 C.F.R. § 1630.2(g).

constitute disabilities protected by the ADA: pedophilia, pyromania, kleptomania, compulsive gambling, homosexuality, bisexuality, transvestism, transsexualism, exhibitionism, voyeurism, and certain other physical, psychological, environmental, cultural, and economic characteristics, including “common personality traits such as poor judgment or quick temper.”³⁸¹

Applying these screening provisions to the functional neuroimaging context yields interesting results. The ADA’s screening provisions would regulate a covered employer’s use of fMRI test results 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 employer attempts to screen out individuals based on fMRI “findings” of pedophilia, compulsive gambling, or homosexuality because these qualities do not constitute impairments or disabilities.

Title I of the ADA also regulates the conduct and timing of medical examinations and related inquiries.³⁸² A medical examination is defined as “a procedure or test that seeks information about an individual’s physical or mental impairments or health.”³⁸³ 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, including structural magnetic resonance imaging, 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—conditions frequently studied by fMRI.³⁸⁴ The EEOC also clarifies, however, that psychological tests designed and used only to measure honesty, tastes, and habits—characteristics also studied by fMRI—are not medical examinations.³⁸⁵

How the ADA regulates employers’ use of medical examinations depends on whether the examination is given during the preemployment, preplacement, or employment stage. The ADA generally prohibits an employer from using a medical examination at the preemployment stage to inquire or attempt to determine whether a particular individual has a disability or the nature or severity of such dis-

381. *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); *id.* pt. 1630 app. (section 1630.2(h) Physical or Mental Impairment) (identifying additional characteristics that do not constitute disabilities under the ADA).

382. 42 U.S.C. § 12112(d) (2000); 29 C.F.R. §§ 1630.13-.14.

383. EQUAL EMP. OPPORTUNITY COMM’N, ADA ENFORCEMENT GUIDANCE: PREEMPLOYMENT DISABILITY-RELATED QUESTIONS AND MEDICAL EXAMINATIONS 10, Notice No. 915.002 (1995), available at <http://www.eeoc.gov/policy/docs/medfin5.pdf>.

384. *Id.* at 15.

385. *Id.*

ability.³⁸⁶ Here, the ADA is attempting to exclude irrelevant health criteria from being used for employment decisions.³⁸⁷ The ADA thus would prohibit an employer from requiring a job applicant in the pre-employment stage to submit to an fMRI examination that falls within the definition of a medical examination. However, the ADA's medical examination provisions would appear not to regulate the use of an fMRI to determine honesty or deception at the preemployment stage because the EEOC has stated that a test to detect honesty is not a medical examination.

At the preplacement stage, however, a covered employer is permitted to require a medical examination and to condition an offer of employment on the results of the examination "if all entering employees in the same job category are subjected to" the same examination and the information collected during the examination is maintained separate from personnel records and kept confidential.³⁸⁸ Because medical examinations conducted at the preplacement stage "do not have to be job-related and consistent with business necessity,"³⁸⁹ an employer could require as a condition of employment that an individual consent to a broad-based fMRI screening. However, if certain criteria are used to screen out an individual with one or more disabilities as a result of the examination, "the exclusionary criteria must be job-related and consistent with business necessity" and the individual must not be able to perform the essential job functions even with reasonable accommodation.³⁹⁰ It thus may be permissible under the ADA to condition an offer of employment for the position of fighter pilot on fMRI test results of an applicant's visual cortex response to flying stimuli, although it would not be permissible to use the same fMRI test results as a basis for refusing to employ an individual for a position such as telephone operator that successfully can be performed by an individual who has visual impairments.

Finally, the ADA establishes requirements that apply to medical examinations given during the employment stage. An employer can require a medical examination of a current employee, but only if the medical examination is job-related and consistent with business necessity.³⁹¹ The ADA thus would prohibit an employer from conducting a broad-based fMRI screening of current employees for "any and all thought processes," although an fMRI test specifically designed to de-

386. 29 C.F.R. § 1630.13(a). *See generally* Mark A. Rothstein, *The Law of Medical and Genetic Privacy in the Workplace*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 281 (Mark A. Rothstein ed., 1997) (discussing medical screening in the workplace).

387. 29 C.F.R. § 1630.13.

388. *Id.* § 1630.14(b).

389. *Id.* § 1630.14(b)(3).

390. *Id.*

391. *Id.* § 1630.14 (c).

termine whether an employee remains capable of performing the essential functions of her job would be permissible.³⁹²

In summary, Title I of the ADA does provide some privacy protections for job applicants and current employees who wish to keep some, but not all, of their neuroimaging information private. How these privacy protections apply in the context of functional neuroimaging depends on whether the employer's proposed fMRI test falls within the definition of a medical examination; the stage—preemployment, preplacement, or employment—at which the employer requires the examination; and whether the examination or any exclusionary criteria are job-related and consistent with business necessity. The ADA does not provide complete privacy protections for job applicants and employees in part because it does not prohibit an employer from requiring an individual to sign an authorization for the release of her functional neuroimaging information.³⁹³ State law may fill some of these gaps.³⁹⁴

Although the use of fMRI as a lie detector may not be considered a medical examination regulated by the ADA, such use may be regulated by the Federal Employee Polygraph Protection Act (EPPA). The EPPA prohibits certain employers from requiring employees to submit to lie detector tests,³⁹⁵ which “includes a polygraph, deceptograph, voice stress analyzer, psychological stress evaluator, or 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.”³⁹⁶ The EPPA could be interpreted to prohibit covered employers from requiring functional neuroimaging examinations that could form the basis of an opinion regarding an individual's dishonesty.

The EPPA does not, however, completely protect all employees from having to participate in fMRI lie detection tests. The EPPA does not apply “to the United States Government, any State or local government,” or any political subdivision of a State or local government, when it is acting as an employer.³⁹⁷ The EPPA also does not prohibit the federal government from requiring a lie detector test of any employee, expert, or consultant under contract with—or assigned or detailed to—the Department of Defense, the Department of Energy, the

392. See *id.* pt. 1630 app. (section 1630.10-.14(d)).

393. Rothstein, *supra* note 386, at 290.

394. For example, the Minnesota Human Rights Act, which is more protective of employees than many other state laws, prohibits employers from requiring or requesting an individual to undergo a medical examination that is not job-related. MINN. ST. § 363A.08(4)(a)(1), -.20(8)(a)(1)(ii), -.20(8)(a)(3) (2005).

395. 29 U.S.C. § 2002(1) (2000).

396. *Id.* § 2001(3).

397. *Id.* § 2006(a).

National Security Agency, the Defense Intelligence Agency, the National Imagery and Mapping Agency, the Central Intelligence Agency, or the Federal Bureau of Investigation.³⁹⁸ Finally, the EPPA does not prohibit the use of polygraph tests on prospective employees “by any private employer whose primary business purpose” involves the provision of “armored car personnel, personnel engaged in the design, installation, and maintenance of security alarm systems, or other uniformed or plainclothes security personnel . . . whose function includes the protection of” certain facilities relating to electric or nuclear power, the public water supply, “radioactive or other toxic waste materials,” or public transportation.³⁹⁹

The EPPA thus provides some protection for non-public sector employees who wish to keep the honesty or deceptiveness of their thoughts to themselves. However, the EPPA provides few privacy protections for federal, state, and local government employees, as well as applicants and employees that provide certain security services in the private sector. This lack of protection is significant given that two commercial fMRI companies are marketing their fMRI lie detectors to federal, state, and local law enforcement agencies.⁴⁰⁰

C. *The Insurance Context*

There has been some speculation that health and life insurance companies will require applicants for insurance to submit to fMRI examinations or authorize the disclosure of their functional neuroimaging information to determine the existence of conditions that might require coverage or payouts in the near future.⁴⁰¹ Others speculate that car insurance companies might require fMRI to predict drivers’ propensity to violence, aggression, or conscientiousness.⁴⁰²

Although HIPAA prohibits group health plans from excluding individuals from a group or charging them higher premiums based on health status-related factors⁴⁰³ and the ADA in theory “extends its prohibition of disability discrimination to employer-provided fringe benefits,”⁴⁰⁴ privacy protections in the insurance context are far from complete. For example, HIPAA does not protect individuals who are not affiliated with an entity providing group coverage, and the ADA

398. *Id.* § 2006(b)-(c).

399. *Id.* § 2006(e)(1).

400. *See supra* notes 123-24 and accompanying text.

401. *See, e.g.,* Turhan Canli & Zenab Amin, *Neuroimaging of Emotion and Personality: Scientific Evidence and Ethical Considerations*, 50 *BRAIN & COGNITION* 414, 424 (2002).

402. *See, e.g.,* Helen Phillips, *Private Thoughts, Public Property*, *NEW SCIENTIST*, July 31, 2004, at 38.

403. 29 U.S.C. § 1182(b) (2000); 29 C.F.R. § 2590.702(b)(2)(i)(B) (2006).

404. Mary Crossley, *Discrimination Against the Unhealthy in Health Insurance*, 54 *U. KAN. L. REV.* 73, 92-95 (2005).

has been interpreted to accept some actuarially justified discrimination even in employer-provided health insurance.⁴⁰⁵ In addition, many evidence of insurability forms used by issuers of health and life insurance coverage in the individual market already require applicants to indicate whether they have ever undergone any scans or magnetic resonance imaging.⁴⁰⁶ If the individual so indicates, the insurer can require the individual to authorize the disclosure of the scans and related records for use in coverage decisions.⁴⁰⁷ Comprehensive privacy protections for neuroimaging information, thus, do not exist in the insurance context.⁴⁰⁸

VI. IDENTITY

In Part V I explored some of the protections available to an individual who wishes to control or avoid the collection of her functional neuroimaging information by third parties, including providers, scientists, employers, and insurers. Here, I explore the implications of fMRI for an individual's identity, or life narrative. Identity issues raised in the functional neuroimaging context include the possibility that fMRI will reveal back to the individual who is the subject of the functional neuroimaging information one or more stories that are inconsistent with the individual's dominant life narrative. As discussed in more detail below, fMRI may construct potentially unwanted identities for an individual without her consent.

It goes without saying that an fMRI examination, like other diagnostic tests and procedures, can reveal important information related to the purpose of the examination back to the subject of the information. Consider an individual who suffers from major depression that is resistant both to drugs and psychotherapy. Functional MRI is one clinical tool that might be proposed to identify the particular neural networks that are going awry. In theory, the radiologists and neurologists would discuss with the individual as part of the informed consent process the functional neuroimaging examination as well as its purpose, risks, and benefits, including the possibility of identifying the areas of the brain that may be contributing to the individual's depression. If the fMRI results are interpreted to locate an abnormal pattern of neural activity, this information would be conveyed back to the patient following the examination (perhaps to help the indi-

405. *Id.* at 95.

406. *See, e.g.*, INDUST. ALLIANCE INS. & FIN. SERVS., INC., EVIDENCE OF INSURABILITY 2, available at <http://www.industrielle-alliance.com/pdf/collectifs/collective/administrateurs/formulaires/54-002A.pdf> (last visited June, 2007).

407. *See* 45 C.F.R. § 164.508(b)(4)(ii), -(iii); Rothstein, *supra* note 228, at 155.

408. *But see* Roberta B. Meyer, *The Insurer Perspective*, in GENETICS AND LIFE INSURANCE: MEDICAL UNDERWRITING AND SOCIAL POLICY 27, 36-39, 45-46 (Mark A. Rothstein ed., 2004) (exploring the use of genetic information in life insurance underwriting).

vidual to decide whether to undergo experimental deep brain stimulation to modulate the affected area).⁴⁰⁹ Although the individual would not know before the examination whether a particular part of her brain was functioning abnormally, the fact that she consented to the examination knowing the purpose of the examination suggests that she considered the possibility of learning that she has an abnormally functioning brain region.

Now consider a situation in which a scientist using fMRI observes a condition or characteristic that is *unrelated* to the purpose or variables of the study. For example, an individual might consent to fMRI research designed to test a hypothesis relating to motor function, but the scientist also might interpret the fMRI as revealing that the individual has schizophrenia or pedophilia or prefers a particular brand of soft drink. Although many diagnostic tests and procedures in theory have the ability to detect incidental findings, experimental brain scans have been found to detect incidental findings such as arteriovenous malformations, brain tumors, and developmental abnormalities in almost half of the scans (47%) examined.⁴¹⁰ Unfortunately, not all investigators have established policies and procedures to be followed in the event of an incidental finding.⁴¹¹

When an incidental finding occurs, the general consensus seems to be that it is ethically desirable to notify the subject of the incidental finding if the finding is “abnormal.”⁴¹² This consensus appears to be based on the ethical principle of respect for persons⁴¹³ as well as recent studies examining subjects’ expectations regarding incidental findings in neuroimaging research. In one study published in 2006, 105 healthy individuals who had previously participated in neuroimaging studies were questioned about their expectations and attitudes regarding incidental findings associated with such studies.⁴¹⁴ The authors found that 54% of the participants reported that they expected research scans to detect abnormalities if they existed and that more than 90% of the participants reported that they would want incidental findings communicated to them.⁴¹⁵ These findings do support the development of a special informed consent process that

409. Dobbs, *supra* note 67 (describing one woman’s experience with experimental deep brain stimulation for her treatment-resistant depression).

410. Illes et al., *Ethical Consideration*, *supra* note 297, at 889.

411. Illes et al., *Discovery and Disclosure*, *supra* note 297, at 745.

412. Illes et al., *supra* note 296, at 783.

413. OFFICE OF HUM. SUBJECTS RES., NAT’L INSTS. OF HEALTH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH Pt. B, § 1 (1979) (“To show lack of respect for an autonomous agent is to . . . withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.”).

414. Matthew P. Kirschen et al., *Subjects’ Expectations in Neuroimaging Research*, 23 J. MAGNETIC RESONANCE IMAGING 205, 205 (2006).

415. *Id.* at 207.

would include making subjects aware of the possibility of potentially clinically significant incidental findings and that would allow them (or the investigator) to decide to refuse to participate in the research depending on the subject's desire to be notified of the unanticipated findings. Indeed, one neuroscientist reportedly tells his subjects, " 'If we find any gross abnormalities in your brain, would you like a radiologist to tell you about it? . . . If you answer no, we cannot do the test. . . . ' "416

The study described in the preceding paragraph classified the subjects' desires to be notified of their incidental findings based on whether the finding was "benign," "malignant, but curable," "malignant, not curable," or a "life-threatening emergency."⁴¹⁷ Much of the discussion therein assumes that the incidental findings would involve "suspicious anatomical abnormalities" or "clinically significant incidental neuroradiological abnormalities," such as an arteriovenous malformation or a brain tumor.⁴¹⁸ However, it is worth noting that the study authors found that fewer individuals (although still more than 90%) would want to know about benign findings compared to malignant and life-threatening findings.⁴¹⁹ The question thus becomes whether individuals also would want to know about findings that are not clinically significant, such as personality, social characteristics, and behavioral information. For example, if a scientist interprets an fMRI as revealing that a particular individual is deceptive, socially cooperative, a risk-seeker, a Democrat, or a compulsive gambler, should the scientist relay that information back to the individual?

In these scenarios, fMRI shows its "impact on our normative conception of identity."⁴²⁰ Recent scholarship shows the extent to which technology, including genetic testing and the Internet, "alter[s] the social structures through which we perceive our identity."⁴²¹ For example, an individual who discovers that she is the carrier of a neurodegenerative disease such as spinocerebellar ataxia type I may be affected even in the absence of physical symptoms.⁴²² After receiving the results that identify her as a carrier, the individual might become depressed and unable to function at school or work or to enjoy social events.⁴²³ The individual, who may view her genes as the essence of her identity, may believe that her genetic information

416. Eric Jaffe, *My Brain Is a Walnut: Inside an fMRI Machine*, SLATE, Jan. 10, 2006, available at <http://www.slate.com/id/2134094>.

417. Kirschen et al., *supra* note 414, at 207-08.

418. *See id.* at 205.

419. *Id.* at 207.

420. *See* Bernstein, *supra* note 236, at 968.

421. *Id.*

422. *Id.* at 987.

423. *Id.*

threatens her decisions, social commitments, and life goals.⁴²⁴ In short, the genetic test results may exert pressure on or destabilize the individual's life narrative.⁴²⁵

Like genetic testing, fMRI also can influence our normative conception of identity. I will use three examples to show how an fMRI can exert pressure on identity. Example A involves an individual, whom I'll call Amy, whose life narrative is governed by the healthy-mindedness meta-narrative. Although individuals do tell their own unique stories, they tend to create their stories by adapting and combining culturally available narrative types.⁴²⁶ One among hundreds of possible meta-narratives is the healthy-mindedness meta-narrative.⁴²⁷ Life narratives governed by the healthy-mindedness meta-narrative tend to revolve around the belief that nature is inherently and absolutely good and around the conquering ability of positive emotions and relentless optimism.⁴²⁸ Healthy-minded individuals tend to believe that loving others, being happy, and thinking optimistically is all that needs to be done to live right.⁴²⁹ When healthy-minded individuals become sick or see others fall ill, they tend to advocate the will to live, the healing power of nature, and the importance of active involvement in all aspects of their treatment.⁴³⁰

Both structural and functional MRI can threaten Amy's healthy-mindedness meta-narrative by revealing a terminal brain tumor from which she will die in a short period of time. Although Amy loves others and pursues optimistic thoughts, her brain tumor continues to develop. Amy's physician has told her that no amount of will to live or active participation in treatment will save her. Amy finds that her body will not heal itself and that "healthy" behaviors such as maintaining hope and eliminating toxins from her diet⁴³¹ do not help. The MRI's revelation of the brain tumor to Amy thus disrupts her coherent sense of her life sequence, including what philosopher David Carr calls a "whole which comprises future, present, and past."⁴³² Like the life narrative of the individual who discovers through genetic testing that she carries a neurodegenerative disease, Amy's life narrative also has been threatened. MRI technology has affected Amy's sense

424. *Id.* at 987-98.

425. *See id.* at 988.

426. FRANK, *supra* note 239, at 75.

427. *See* ANNE HUNSAKER HAWKINS, RECONSTRUCTING ILLNESS: STUDIES IN PATHOGRAPHY 125-57 (2d ed. 1999).

428. *Id.* at 127.

429. *Id.*

430. *Id.* at 128-29.

431. *See id.* at 128 (including these beliefs in the typical healthy-mindedness meta-narrative).

432. DAVID CARR, TIME, NARRATIVE, AND HISTORY (STUDIES IN PHENOMENOLOGY AND EXISTENTIAL PHILOSOPHY) 96 (1st Midland Book ed. 1991).

of stability, motivation, and purpose in life, which was derived from her healthy-mindedness, and may require Amy to adopt new, and perhaps very different, life choices in her remaining time.⁴³³

The tumor example was possible given brain examinations via either structural or functional MRI. The unique ways in which functional MRI threatens identity can be illustrated by a second example, Example B, involving addictive behavior. Think of a scientist conducting a neuromarketing study who uses fMRI to scan the brain of an individual, I'll call her Bea, while a computer shows Bea a series of product images, including bottled water, juices, soft drinks, and alcoholic beverages produced by national and local beverage manufacturers. The study is designed to test a hypothesis relating to brand familiarity. Assume, however, that upon presentation of all of the alcoholic beverage images the scientist observes a very significant BOLD response in the areas of Bea's brain known to be related to attention and interest—which the scientist interprets as revealing that Bea is an alcoholic.

Also assume, however, that Bea ten years ago successfully completed treatment and counseling for alcohol abuse. Although Bea's brain still "lights up" when she sees alcoholic beverages, Bea has adopted behaviors that help her avoid drinking. When she is presented with a situation in which alcohol is available, Bea calls her Alcoholics Anonymous (AA) sponsor, attends an AA meeting, or diverts her attention to another task until the availability of alcohol has passed. These procedures have helped Bea abstain from alcohol for ten years and lead a full and healthy life involving work, family, and social activities. Although Bea freely admits that she is vulnerable to alcohol, she has succeeded in avoiding drinking long-term by adopting the behaviors learned through AA.

Following her fMRI examination, however, assume that Bea loses her confidence regarding her ability to abstain from drinking. She thinks that her brain is "hardwired" to drink and fears that alcohol will reassert its control over her life. Although Bea was confident that she could continue avoiding alcohol before the fMRI examination, now she feels that she always will be "just an alcoholic" and that she should not try to fake being healthy anymore. Bea withdraws from her friends and family and refuses to leave her apartment except to go to work for fear that she will again succumb to alcohol.

In Example B, the fMRI has constructed an identity for Bea based on her BOLD signal response to alcoholic beverage images, notwithstanding that Bea's own ten-year life narrative revolved around her success in avoiding drinking and her new, healthy lifestyle. The iden-

433. Cf. Bernstein, *supra* note 236, at 988 (concluding that an "identity transformation period . . . occurs when acute pressure is exerted on one's life-narrative").

tity constructed by the fMRI in Example B conflicts with, and exerts a negative pressure on, Bea's self-perceived identity. However, Bea might think that the identity constructed by the fMRI is not really a surprise given that she knows she always will be vulnerable to alcohol.

A final example, Example C, shows how fMRI has the potential to construct surprise identities. In Example C a scientist scans the brain of a woman I'll call Clare while a computer shows Clare a series of images of attractive and unattractive men and women. The scientist is trying to test a hypothesis relating to the effect of pleasing and unpleasing faces on the brain. While testing this hypothesis, however, the scientist also observes a significant BOLD response in the regions of Clare's brain known to be correlated with sexual attraction whenever Clare is presented with an image of a woman. The scientist interprets the results as revealing that Clare is homosexual.

Assume, however, that Clare, who is married to a man, believes that she is heterosexual and that Clare's friends and family are hostile to homosexuals and neither value nor respect same-sex attractions or relationships. Also assume that Clare's life narrative is governed by a communitarian meta-narrative. Clare understands her identity as constituted by her community, including her friends and family. Clare is bound by community obligations and is guided by community values.⁴³⁴ Finally, assume that Clare becomes unhappy following the fMRI exam because she feels that the exam constructed for her an unwanted identity without her consent. Clare feels that the scientist's fMRI interpretation is forcing her to reconsider her sexual identity when she thought she was happily married to her husband. Clare also is worried regarding how her technologically constructed identity, if adopted, might conflict with the values of her family. In Example C, then, the fMRI has both challenged Clare's heterosexual identity and threatened her communitarian meta-narrative. Although the fMRI interpretation potentially revealed new insights to Clare about her sexuality, Clare might think that these insights present agonizing and unwanted dilemmas at this point in her life.

The theory that identity pressures merit our normative concern is well supported in the literature.⁴³⁵ The prevailing theory is that individuals need a coherent sense of their life sequence.⁴³⁶ Life narratives provide this coherence and meaning to our lives and relationships.⁴³⁷ When our life narratives are threatened or disrupted, frustration and discontent can occur, even if no financial harm has resulted.⁴³⁸ Fol-

434. *See id.* at 989-90.

435. *See, e.g.,* FRANK, *supra* note 239, at 60; Bernstein, *supra* note 236, at 993-1000.

436. FRANK, *supra* note 239, at 60.

437. Bernstein, *supra* note 236, at 993.

438. *Id.* at 994.

lowing these interruptions, determined attempts to recreate new meaning and coherence usually follow.⁴³⁹

The question thus becomes whether existing legal principles sufficiently protect an individual's interest in controlling the construction of her identity.⁴⁴⁰ In Parts IV and V, I showed that existing confidentiality and privacy principles attempt to regulate the use and disclosure of functional neuroimaging information by third parties and the collection of functional neuroimaging information by third parties, respectively. As I have defined these principles, they do not regulate the revelation of functional neuroimaging information back to the individual who is the subject of the information.⁴⁴¹ However, the doctrine of informed consent may.

Informed consent is the process pursuant to which a patient or research subject makes a competent, voluntary, and informed decision to pursue a particular medical treatment (informed consent to treatment) or to participate in a particular research study (informed consent to research).⁴⁴² Informed consent to treatment principles generally require the physician to disclose to the patient her diagnosis, if known; the nature, purpose, risks, and benefits of the proposed medical treatment or surgical procedure; alternatives to the proposed treatment or procedure and their risks and benefits; and the risks and benefits of not receiving or undergoing any treatment or procedure.⁴⁴³ Risks generally are defined as risks that would be material to a reasonable person in deciding whether to undergo the procedure.⁴⁴⁴ Regulatory informed consent to research principles are slightly more complex and require, among other things,⁴⁴⁵ a statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable.⁴⁴⁶

439. See, e.g., HAWKINS, *supra* note 427, at 2-3.

440. Cf. Jonathan Kahn, *Controlling Identity: Plessy, Privacy, and Racial Defamation*, 54 DEPAUL L. REV. 755 (2005) (examining identity control as an explicit legal interest); Bernstein, *supra* note 236, at 968 (arguing for "the incorporation of identity protections into the legal discourse governing genetic testing and the Internet").

441. But see Kahn, *supra* note 236, at 373 ("Privacy, in short, provides principles for negotiating the legal management of personhood in a manner that facilitates the development and maintenance of a coherent individual identity essential to our liberal polity's commitment to human flourishing.")

442. See generally MARSHA GARRISON & CARL E. SCHNEIDER, *THE LAW OF BIOETHICS: INDIVIDUAL AUTONOMY AND SOCIAL REGULATION* 27-150 (2003) (examining in detail the concepts of informed consent to treatment and research).

443. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 787-88 (D.C. Cir. 1972); see generally TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 77-83 (5th ed. 2001) (examining the doctrine of informed consent); GARRISON & SCHNEIDER, *supra* note 442, at 27-150 (examining the doctrine of informed consent).

444. See BEAUCHAMP & CHILDRESS, *supra* note 443, at 82.

445. 45 C.F.R. § 46.116(a)-(b) (2006) (listing the Common Rule's basic and additional elements of informed consent).

446. *Id.* § 46.116(b)(1).

The informed consent principles as described above do not expressly require a physician or scientist to tell her patient about the possibility of incidental findings or the pressure they place on life narratives. However, these principles could be interpreted or expanded to do so. As discussed above, informed consent to research principles already require the potential research subject to be notified of risks that are currently unforeseeable. Technology-imposed identity pressures can impose risks of harm, although the possibility of, kind, and extent of harm the individual suffer may be unforeseeable. The reference to unforeseeable risks in informed consent to research principles thus could be interpreted to include incidental findings that may exert pressure on an individual's life narrative. In summary, a broadly interpreted notion of informed consent to research—and an expanded notion of informed consent to treatment—could be used to address the identity concerns raised by structural and functional brain scanning.

Once individuals are informed about the possibility of incidental findings, they can attempt to control the revelation of those findings back to themselves. Of course, a legal document that identifies in writing the possibility of fMRI incidental findings would not, standing alone, allow an individual to control the receipt of incidental findings.⁴⁴⁷ An ethically desirable informed consent process would make each individual personally aware of the possibility of incidental findings, provide examples of information that may be incidentally discovered, and navigate the boundaries of the individual's right to control her receipt of that information.⁴⁴⁸ For example, the parties could negotiate a notification processes to be followed in the event of both clinically significant and insignificant findings. Individuals who feel that they are not vulnerable to changes in their life narratives may request to receive both clinically significant and insignificant findings. At the same time, individuals who are vulnerable to changes in their life narratives may elect to receive clinically significant incidental findings but not findings relating to personal character-

447. See, e.g., Paul J. Ford & Jaimie M. Henderson, *Functional Neurosurgical Intervention: Neuroethics in the Operating Room*, in *NEUROETHICS: DEFINING THE ISSUES IN THEORY, PRACTICE, AND POLICY* 213, 226 (Judy Illes ed., 2006) (“The ethical issues cannot be reduced to or solved by impeccable informed consent or some formulaic ethics process.”).

448. An individual's request to access protected health information in the possession of a covered entity can implicate the Privacy Rule. See 45 C.F.R. § 164.502(a), -(a)(2)(i) (“A covered entity is required to disclose protected health information . . . [t]o an individual, when requested”); *id.* § 164.524(a)(1) (stating that “an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set”). But see *id.* § 164.524(a)(2)(iii) (“An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial . . . when consenting to participate in the research”).

istics and traits. Individuals who do not wish to be notified even of clinically significant findings may wish to decline to participate in the research.⁴⁴⁹

VII. A CASE FOR NEURO EXCEPTIONALISM?

A number of ethical and legal principles potentially apply to protect confidentiality, privacy, and identity in the functional neuroimaging context. Are these protections adequate? Are additional protections needed? To answer these questions, I first must address the scope of the confidentiality, privacy, and identity concerns raised by fMRI examinations.

A. *A Technological Straw Man?*

The scope of the confidentiality, privacy, and identity concerns raised by fMRI depends, in part, on the information that the technology has the potential to reveal.⁴⁵⁰ If an fMRI only was capable of mapping speech, language, and motor functions to assist with neurosurgery or of identifying neurological impairments, then the confidentiality, privacy, and identity concerns raised thereby would be very similar to those raised by traditional, albeit sensitive, medical record information. Policies and procedures designed to protect sensitive information, such as mental health records, would be instructive and, perhaps, sufficient to protect neuroimaging information if their application was extended.

On the other hand, if fMRI somehow became a generally accepted technology for identifying an individual's sexual preferences, evaluating the morality of her decisions, or measuring the deceitfulness of her actions, the technology would challenge existing confidentiality and privacy schemes, which tend to protect health information, not social characteristics and behaviors. Because we cannot predict exactly how quickly and accurately fMRI technology will develop, we are left to debate whether the threats to the confidentiality of neuroimaging information and to cognitive privacy are real or imagined.⁴⁵¹ The development of commercial fMRI lie detectors was believed to be several years away at the time I began to research this Article. Now, one company is directly marketing its brain scanning services to the

449. Or their physicians and scientists may elect not to treat or study them for risk management purposes.

450. See Buller, *supra* note 126, at 58.

451. Joseph J. Fins, *The Orwellian Threat to Emerging Neurodiagnostic Technologies*, AM. J. BIOETHICS, Mar.-Apr. 2005, at 56, 57 ("Is the threat of an invasion of cognitive privacy real or *imagined* in the minds of savvy neuroethicists looking to create a new variation on a bioethics theme?").

general public.⁴⁵² This threat to cognitive privacy has gone from imagined to real in the space of two years.

The scope of the confidentiality, privacy, and identity concerns raised by fMRI also depends on the technology's perceived potential. Even though fMRI may never be capable of accurately reading an individual's mind, confidentiality, privacy, and identity may be threatened if private organizations and governmental agencies believe that it is. A mandatory fMRI that accurately reveals an individual's thoughts is one thing. A mandatory fMRI that is incorrectly interpreted to reveal what is believed to be the individual's thought, characteristic, or behavior and that is used to her detriment in an employment, criminal justice, or insurance capacity is another.⁴⁵³ The fMRI, like other sophisticated technologies, "possess[es] an illusory accuracy and objectivity"⁴⁵⁴ that can be dangerous in the hands of employers, insurers, jurors, lawyers, judges, and government officials who lack the scientific and statistical training necessary to understand published fMRI studies and interpret fMRI test results.⁴⁵⁵ Yet, these are the individuals to whom commercial fMRI lie detectors are currently being marketed.⁴⁵⁶ For these reasons, I do not believe that the act of identifying and carefully discussing the confidentiality, privacy, and identity implications of fMRI contributes to the creation of technological straw men.⁴⁵⁷

B. Responsible Discussion

In Part III I found that some of the scientists who conduct neuroimaging studies use care when publishing their findings and even expressly caution against inappropriate or too eager interpretations and applications of fMRI. However, I also found that descriptions of neuroimaging research in the popular media—including physicians', lawyers', bioethicists', and some scientists' statements to the media—are not as constrained.⁴⁵⁸ I argued in Part III that scientists need to continue the care with which they describe their research findings

452. No Lie MRI, *supra* note 122.

453. See generally Steve Olson, *Brain Scans Raise Privacy Concerns*, 307 SCI. 1548 (2005) (noting the concern that people may mistakenly trust incorrectly interpreted results).

454. Martha J. Farah, *Emerging Ethical Issues in Neuroscience*, 5 NATURE REV. NEUROSCIENCE 1123, 1127 (2002).

455. Greely, *supra* note 237, at 118-20.

456. See *supra* notes 123-24 and accompanying text; Malcolm Ritter, *Brain Scans as Lie Detectors: Ready for Court Use?*, LIVE SCI., Jan. 29, 2006, http://www.livescience.com/humanbiology/060129_brain_lie.html.

457. See generally Fins, *supra* note 451, at 57 ("One wonders if bioethicist critics are creating another technological straw man to undermine.").

458. Cf. Rothstein, *supra* note 228, at 793 (identifying a similar phenomenon in genetics).

and the diligence with which they identify appropriate and inappropriate uses of neuroimaging information.⁴⁵⁹

Here, I want to emphasize that neuroscientists have a role in the public, not just the scientific, arena, which includes identifying limitations and cautioning against unwarranted extensions of research findings.⁴⁶⁰ Scientists, rather than non-scientifically trained lawyers and ethicists, are in the best position to clarify how research findings should be interpreted.⁴⁶¹ In the context of genetics, some have proposed that scientists study during graduate school “the social implications of science and the historical instances where scientists have spoken out.”⁴⁶² This proposal makes sense in the context of neuroscience too. Many graduate science students take a required one-credit course in the ethics of scientific research, which may cover topics such as “the philosophy of science, practice of scientific research, conflicts of interest, and the value conflicts that arise between scientists and society at large.”⁴⁶³ The course I took did not specifically address how private and governmental institutions may attempt to incorporate scientific findings into their business decisions or the role scientists play in describing their research to the media and identifying appropriate and inappropriate uses of scientific information. These topics can—and should—be included in graduate science education.

I have focused on the social responsibilities of scientists, but lawyers, bioethicists, and others who contribute to media reports and the neuroethics literature have equal responsibilities. We need to ensure that our excitement about fMRI, as expressed through statements to the media and during other public discussions, does not increase the risk of therapeutic illusions, therapeutic extravagance, and therapeutic futility. Therapeutic illusions exist when patients, family members, and other stakeholders believe that a particular medical treatment or research protocol will improve a patient’s condition, when in all likelihood it will have no beneficial effect.⁴⁶⁴ Therapeutic extravagance involves “the provision of high-cost treatments that of-

459. *Cf. id.* at 797 (advising genetics researchers to make careful public pronouncements regarding their research and to “temper their enthusiasm for the potential implications of preliminary studies”).

460. *Cf. Jon Beckwith & Franklin Huang, Should We Make a Fuss? A Case for Social Responsibility in Science*, 23 NATURE BIOTECHNOLOGY 1479, 1479 (2005) (making a similar argument in the context of genetics).

461. *Id.*

462. *Id.* at 1480.

463. *See* University of Texas Medical Branch, The Institute for the Medical Humanities, Course Descriptions, Ethics of Scientific Research, *available at* <http://www.utmb.edu/imh/GraduateProgram/gp.asp?show=Course-Req> (last visited June 22, 2007).

464. Stacey A. Tovino & William J. Winslade, *A Primer on the Law and Ethics of Treatment, Research, and Public Policy in the Context of Severe Traumatic Brain Injury*, 14 ANNALS HEALTH L. 1, 2 n.5 (2005).

fer little or no benefit.”⁴⁶⁵ Therapeutic futility refers to “the provision of treatments that offer little or no benefit and, thus, are wasteful.”⁴⁶⁶

For example, nonscientists should not suggest that fMRI is capable of distinguishing between persistently vegetative or minimally conscious patients or of assisting them in emerging from unconsciousness when it cannot do so.⁴⁶⁷ Nonscientists should expressly state that they are speculating when they are doing so, attempt to incorporate current science studies into any speculation in which they do engage, and avoid speculation that has no basis in the scientific literature. When *New York Times* reporter Benedict Carey stated that “[a]t this rate, it seems that neuroscientists will soon pinpoint the regions in the brain where mediocre poetry is generated, where high school grudges are lodged, where sarcasm blooms like a red rose,”⁴⁶⁸ I realized that Mr. Carey was exaggerating—given that my research had revealed no fMRI studies examining the neural correlates of poetry, high school grudges, or sarcasm—but the general public may not have.

Of course, the need for caution in identifying and describing scientific findings must be balanced with the need to avoid over-conservative publication and reporting, which could increase the risk of therapeutic nihilism (the failure to recognize the possible benefits of treatment) and therapeutic neglect (a patient’s lack of access to treatment from which she could benefit).⁴⁶⁹ For example, the findings of some fMRI deception studies have the potential to assist patients who have addictive disorders in which deception, or the ability to conceal information, plays a prominent role.⁴⁷⁰ The findings of other fMRI studies involving known pedophiles may provide information that is valuable to their treatment.⁴⁷¹

Although Part III identifies a handful of fMRI studies that have generated the most speculation about their application in nonresearch settings, the media has not covered the thousands of other fMRI studies the goals of which are to further treatment of the studied conditions. Publication and accurate reporting of these studies is

465. *Id.*

466. *Id.*

467. See Fins, *supra* note 451, at 56.

468. Carey, *supra* note 69.

469. See Charles E. Rosenberg, *Belief and Ritual in Antebellum Medical Therapeutics*, in MAJOR PROBLEMS IN THE HISTORY OF AMERICAN MEDICINE AND PUBLIC HEALTH: DOCUMENTS AND ESSAYS 108, 112-13, 117 (John Harley Warner & Janet A. Tighe eds., 2001) (exploring the history of therapeutic nihilism); Tovino & Winslade, *supra* note 464, at 2 n.5.

470. See, e.g., Neil Levy, *Self-Deception and Responsibility for Addiction*, 20 J. APPLIED PHIL. 133 (2003) (noting that individuals who are addicted to drugs and alcohol engage in self-deception); B. Douglas Bernheim & Antonio Rangel, *Addiction and Cue-Triggered Decision Processes*, 94 AM. ECON. REV. 1558, 1558 (2004).

471. See, e.g., Dressing et al., *supra* note 208, at 539.

necessary for progress in medicine and science. Like so many other issues in ethics, then, scientific findings require balanced presentation by scientists and nonscientists.

C. The Analogy to HIV Exceptionalism and Genetic Exceptionalism

HIV exceptionalism and genetic exceptionalism refer to the claims that HIV test results and genetic information are so different from other types of health information that they deserve exceptional measures.⁴⁷² HIV exceptionalism was introduced to health care in the first decade of the epidemic through special “pre- and post-test counseling, anonymous testing, and stringent protections of confidentiality.”⁴⁷³ Genetic exceptionalism was implemented when over forty states passed statutes “prohibiting genetic discrimination in health insurance; two-thirds of the states . . . enacted laws prohibiting genetic discrimination in employment”; and a handful of other states enacted various provisions addressing “genetic discrimination in life insurance, genetic privacy, and genetic testing.”⁴⁷⁴ Congress also has attempted to pass legislation prohibiting genetic discrimination in both the health insurance and employment contexts.⁴⁷⁵

The question thus becomes whether implementation of a third generation of exceptionalism—neuro exceptionalism⁴⁷⁶—is desirable. Are special or heightened confidentiality, privacy, and identity protections necessary to protect functional neuroimaging information? Several reasons have been given for exceptional genetic provisions, and an analysis of these reasons, and their criticisms, can inform the neuro exceptionalism debate.

One argument for genetic exceptionalism relates to genetic prophecy and kin.⁴⁷⁷ According to this argument, genetic information is a “future diary” that can predict an individual’s (and her biological family members’) future physical and mental health conditions and can influence these individuals’ views of their life possibilities.⁴⁷⁸ These future diaries are believed to require special protections.⁴⁷⁹ Critics of the genetic prophecy argument emphasize that replication

472. Thomas H. Murray, *Genetic Exceptionalism and “Future Diaries”: Is Genetic Information Different from Other Medical Information?*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 60, 61 (Mark A. Rothstein ed., 1997).

473. Zita Lazzarini, *What Lessons Can We Learn from the Exceptionalism Debate (Financially)?*, 29 *J.L. MED. & ETHICS* 149, 149 (2001).

474. Mark A. Rothstein, *Genetic Exceptionalism & Legislative Pragmatism*, *HASTINGS CTR. REP.*, July-Aug. 2005, at 27; Greely, *supra* note 237, at 124.

475. *See* Genetic Information Nondiscrimination Act of 2003, S. 1053, 108th Cong. (2003); Genetic Information Nondiscrimination Act of 2005, S. 306, 109th Cong. (2005).

476. Ari Schick, *Neuro Exceptionalism?*, *AM. J. BIOETHICS*, Mar.-Apr. 2005, 36, at 36.

477. Murray, *supra* note 472, at 62.

478. *Id.*

479. *See id.*

studies show that claimed associations between genetic variations and particular diseases do not always exist, many predictions are inaccurate, the strengths of accurate predictions vary greatly, and treatments do not exist for all of the conditions that can be predicted.⁴⁸⁰

Because some fMRI studies involve health conditions in which genes play a role, a brain scan that is used to study or is interpreted to reveal the precursors of one of these conditions could have implications for individuals and their biological family members in a manner similar to genetic information. A genetic basis for brain wiring in humans⁴⁸¹ and the current interest in identifying genetic markers that might be linked to phenotypes that are accessible by fMRI further support this argument.⁴⁸² Speculation that fMRI might be used to predict non-health-related conditions, including intelligence, likelihood of committing future crimes, and social behavior,⁴⁸³ parallel some of the predictive concerns raised by genetics. And, as discussed in Part VI, fMRI can construct alternative narratives that can affect an individual's view of her identity and life's possibilities. On the other hand, the unknown accuracy of fMRI predictions, as well as the lack of available treatments for many of the conditions discovered by fMRI, also must be considered. The first argument for genetic exceptionalism and its criticisms thus apply to some extent in the functional neuroimaging context.

A second reason given for genetic exceptionalism is that genetic information carries a stigma and that eugenics, racism, and genocide are the unfortunate results of the inappropriate use of genetic information.⁴⁸⁴ It is fair to say that fMRI technology probably is still too new for functional neuroimaging information results to carry a widespread stigma; however, this may rapidly change as fMRI use extends outside of the research context and more functional neuroimaging information is created, used, and disclosed in the private and government sectors. Additionally, although functional neuroimaging information may not currently carry a widespread stigma, fMRI scans have been interpreted to reveal neural activations that are correlated with certain mental health conditions, addictive behaviors, cognitive abilities, and sexual preferences, all of which the NIH considers sensitive or stigmatizing in other contexts.⁴⁸⁵ Thus, the second reason for genetic exceptionalism also could support neuro excep-

480. *See id.* at 64-72.

481. *See, e.g.,* Phillip A. Leighton et al., *Defining Brain Wiring Patterns and Mechanisms Through Gene Trapping in Mice*, 410 NATURE 174, 174 (2001).

482. *See* Jezzard & Buxton, *supra* note 41, at 791; Mitterschiffthaler et al., *supra* note 205, at 857-59.

483. Greely, *supra* note 237, at 116.

484. Murray, *supra* note 472, at 62; Rothstein, *supra* note 474, at 30.

485. CERTIFICATES BACKGROUND, *supra* note 342; CERTIFICATES QUESTIONS, *supra* note 343.

tionalism, although research revealed no attempts to improve the human species by encouraging or permitting reproduction of only those individuals whose brain functions are judged desirable through review of fMRI scans (although, of course, related speculation does exist).⁴⁸⁶

A third reason given for genetic exceptionalism is that the public regards it as unique.⁴⁸⁷ Although the public might not currently regard functional neuroimaging information as unique due to the relative newness of fMRI technology, the public may in the near future consider it so due in part to the frequency with which fMRI studies are covered by the media, including the *New York Times*, which has featured fMRI technology in at least fifty-two articles.⁴⁸⁸ Of course, relying on public regard as a reason for heightened confidentiality and privacy protections has been criticized on the grounds that it is self-fulfilling.⁴⁸⁹ Stated another way, the public might regard specific types of information as unique because information-specific legislation or regulation is passed.⁴⁹⁰

A fourth reason given for heightened protection for genetic information is that other sensitive or potentially stigmatizing types of health information receive special protection. Congress has enacted special protections that apply to certain alcohol and drug abuse patient records;⁴⁹¹ many states have passed laws that provide special confidentiality protections for HIV/AIDS test results⁴⁹² and mental health records;⁴⁹³ and even the HIPAA Privacy Rule, which generally applies one uniform level of protection to all types of individually identifiable health information, provides heightened confidentiality protections for psychotherapy notes.⁴⁹⁴ However, critics argue that genetic information is unlike these other types of information, which can be separated from general medical records with relative ease.⁴⁹⁵ Because genes play a role in many diseases and genetic information can be based on family history or revealed through thousands of different types of tests, it is more difficult for health care providers to separate genetic information from general health information.⁴⁹⁶ Unlike genetic information, however, fMRI scans and their related

486. TANCREDI, *supra* note 8, at 162-75 (describing a hypothetical legislative program set in the year 2100 that would attempt to create a moral brain).

487. Rothstein, *supra* note 474, at 30.

488. Westlaw New York Times database search results for query "fMRI" or "functional MRI" or "functional magnetic resonance imag!" or "functional neuroimag!" (performed Oct. 17, 2006).

489. Rothstein, *supra* note 474, at 30.

490. *Id.*

491. 42 C.F.R. pt. 2 (2006).

492. *See, e.g.*, TEX. HEALTH & SAFETY CODE ANN. §§ 81.103-106 (Vernon 2005).

493. *See id.* §§ 611.002-.003.

494. 45 C.F.R. § 164.508(a)(2) (2006).

495. Rothstein, *supra* note 474, at 30; Rothstein, *supra* note 350, at 459.

496. *See sources cited supra* note 495.

reports could be maintained separately from general medical records with relative ease.

Other arguments support genetic exceptionalism. For example, greater political support may exist for genetic nondiscrimination legislation than for more general legislation.⁴⁹⁷ Those working within the field of neuroethics are clearly grappling with the pros and cons of neuro exceptionalism,⁴⁹⁸ although it is unclear whether more (or any) political support currently exists for neuro-specific legislation compared to general confidentiality and privacy protections.

In summary, many of the reasons given for genetic exceptionalism also could be used to support neuro exceptionalism, although many of the criticisms of genetic exceptionalism also apply in the functional neuroimaging context. Perhaps the most important factor—whether existing confidentiality, privacy, and identity protections adequately protect neuroimaging information and the individuals whose brains have been scanned—has been overlooked.

D. *Neuro Exceptional and Generic Options*

As shown in Part IV, the Common Rule, the Privacy Rule, state licensing laws, and Public Health Service provisions establishing certificates of confidentiality do contain provisions that may protect the confidentiality of some functional neuroimaging information. However, the Common Rule, the Privacy Rule, and state licensing laws regulate a limited class of individuals and organizations. Both the Privacy Rule and state licensing laws contain a number of exceptions to confidentiality, many of which may be implicated in the functional neuroimaging context. And, neither the Privacy Rule nor many state laws prohibit individuals from authorizing disclosures of their functional neuroimaging information to third parties, such as employers and insurers. Functional neuroimaging information, thus, has incomplete confidentiality protections.

Efforts to expand the application of the Common Rule, the Privacy Rule, and state licensure laws to regulate all of the individuals and organizations who wish to create and use functional neuroimaging information currently are not likely to be successful.⁴⁹⁹ Efforts to establish stand-alone, heightened confidentiality protections for functional neuroimaging information might have a greater chance of success, although the desirability of, and practical issues raised by, such

497. See Rothstein, *supra* note 474, at 30.

498. See, e.g., Schick, *supra* note 476, at 36.

499. See, e.g., Standards for Privacy of Individually Identifiable Health Information 65 Fed. Reg. 82,462, 82,567 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160 & 164) (“We understand that many entities [other than covered entities] may use and disclose individually identifiable health information. However, our jurisdiction under the statute is limited to [covered entities].”).

efforts require evaluation too. One option thus is to give functional neuroimaging information heightened confidentiality protections. The Privacy Rule already regulates the use and disclosure of psychotherapy notes—personal notes that help the therapist recall a therapy discussion and may relate, for example, to the content of a client’s dream—more stringently than other types of health information.⁵⁰⁰ Perhaps federal or state laws could treat functional neuroimaging information like psychotherapy notes. Psychotherapy notes actually make a nice analogy to some types of functional neuroimaging information, especially fMRI test results that are interpreted to reveal an individual’s thoughts and feelings. Consideration of this neuro exceptional proposal requires several hurdles to be cleared.

One hurdle is that any heightened confidentiality protections would need to be balanced against the legitimate activities for which the law already supports the use and disclosure of health information. For example, if fMRI could accurately—and the key word is accurately—determine whether an individual is a rapist or murderer, public policy might support the use and disclosure of the individual’s functional neuroimaging information for law enforcement purposes.⁵⁰¹ On the other hand, public policy might support maintaining the confidentiality of functional neuroimaging information in situations in which fMRI remains an experimental cognitive neuroscience tool. Proposed neuro exceptional confidentiality provisions thus need to be rebalanced against stated needs to use and disclose health information as required by law and for needs relating to reimbursement, health care operations, public health, the detection of victims of abuse and neglect, health oversight, judicial and administrative proceedings, law enforcement, research, serious threats to health and safety, specialized government functions, and workers’ compensation.⁵⁰²

A neuro exceptional confidentiality provision also would require a corresponding definition of protected *functional neuroimaging information*. In genetic exceptionalism, defining *genetic information* has proved difficult, in part because it requires a determination of whether genetic information should be narrowly defined to include only genetic test results or broadly defined to include family history. Defining *functional neuroimaging information* should be easier, although decisions still would need to be made about the types of functional neuroimages—such as fMRI, positron emission tomography (PET), and single-photon emission computed tomography (SPECT)

500. 45 C.F.R. § 164.508(a)(2) (2006).

501. See, e.g., 45 C.F.R. § 164.512(f) (2006) (Privacy Rule provision allowing protected health information to be used and disclosed without patient authorization for certain law enforcement activities).

502. See, e.g., *id.* §§ 164.506, -512(a)(l) (Privacy Rule provisions attempting to balance confidentiality rights against various needs to use and disclose information).

images—that would be included, and about the scope of included interpretations and reports. Protecting image interpretations and related reports would seem to be important given that many fMRI images are meaningless without knowledge of the mental tasks that were assigned to the individual during the examination, the timing of the BOLD contrast, and the radiologist or scientist's interpretation of such contrast.

The main problem with blanket neuro exceptional confidentiality provisions is that many of the conditions and characteristics that have the potential to be revealed by fMRI are not that exceptional. Neurological conditions and disorders such as a brain tumor, stroke, persistent vegetative state, minimally conscious state, depression, schizophrenia, bipolar disorder, alcohol addiction, cocaine addiction, and compulsive eating can be sensitive and stigmatizing. However, they are not terribly unique, especially in the neurology and psychiatry settings. Applying heightened confidentiality protections to an expensive fMRI test that reveals a brain tumor but not to a less expensive x-ray examination that reveals the same brain tumor also could give providers incentive to use less expensive (and less sensitive) diagnostic equipment to avoid neuro exceptional administrative costs.

What is unique about fMRI is its potential to reveal insights about an individual's thoughts, feelings, preferences, prejudices, and other social characteristics and behaviors. Neuro exceptional confidentiality provisions that protect just these insights might garner more support, although crafting a definition of *functional neuroimaging information* that includes only unique insights (and not routine neurological impairments) would be difficult.

Neuro exceptional privacy provisions might be easier to craft. Because confidentiality provisions continue to allow providers and scientists to disclose functional neuroimaging information pursuant to compelled authorizations, one privacy option is to prohibit employers, insurers, and other organizations from collecting fMRI test results pursuant to voluntary and compelled authorizations. A second option is to prohibit these organizations from conducting their own fMRI examinations of applicants for employment, insurance, and other benefits. The EPPA prohibition against use by private employers of lie detection devices and test results might be used as a model for a law codifying these two options.

A broad example of such a law (perhaps, the "Functional Neuroimaging Protection Act") could make it unlawful for employers and insurers to require, request, suggest, or cause any employee, inseree, or applicant for employment or insurance to take or submit to any functional neuroimaging test or to use, accept, refer to, or inquire concerning the results of any functional neuroimaging test. The law

would require a corresponding definition of *functional neuroimaging test* as well as clarification regarding the neuroimaging technologies and testing procedures that would constitute *functional neuroimaging tests*. A narrower version of such a law could prohibit employers, health insurers, and life insurers from using any health or social information, including functional neuroimaging information for non-job-related purposes at any stage of employment, to deny basic health insurance coverage, or to deny one small life insurance policy, respectively.⁵⁰³

VIII. CONCLUSION

As fMRI poses minimal health risks,⁵⁰⁴ its most significant risks may be potential breaches of confidentiality, invasions of cognitive privacy, and the construction of alternative identities. I thus recommend (1) implementation and enforcement of existing confidentiality and privacy rights while neuro exceptional proposals are being considered; (2) the development of non-neuro exceptional provisions that prohibit the use of health and social information by employers for non-job-related purposes at any stage of employment, by health insurers to deny basic health insurance coverage, and by life insurers to deny one small life insurance policy; and (3) the incorporation of incidental findings within the doctrine of informed consent.

My first recommendation—implementation and enforcement of existing confidentiality and privacy rights—is an efficient interim measure. Health care providers and scientists must be made aware of the confidentiality, privacy, and identity issues raised by fMRI and should develop internal measures to protect their patients and research subjects. These measures, which should be designed to respond to the obvious confidentiality and privacy risks posed by fMRI, should address the removal of raw facial image elements and other identifiers from neuroimaging information; the establishment of best practices relating to the short and long-term storage of raw neuroimaging data; the development of policies and procedures relating to incidental findings, including policies and procedures for notification of the individual who is the subject of the findings and the process for treatment referral; and the application for certificates of confidentiality by scientists who create sensitive functional neuroimaging information.

My second recommendation—the development of generic privacy protections in the employment, health, and life insurance contexts—responds to gaps in existing confidentiality and antidiscrimination

503. See also Rothstein, *supra* note 350, at 478 (making a similar recommendation in the context of genetics).

504. Norris, *supra* note 12, at 794 (“studies on healthy subjects can be performed without harmful side effects”).

laws that allow employers and insurers to force individuals to authorize disclosures of their health information, including their functional neuroimaging information. I recommend generic, rather than neuro exceptional, privacy provisions to avoid a number of substantive, practical, and administrative concerns. These concerns include protecting functional neuroimaging information that is not exceptional, crafting a definition of *functional neuroimaging information* that protects only unique information, and imposing higher administrative costs on providers and scientists who use fMRI.

My third recommendation—incorporation of incidental findings within the doctrine of informed consent—will help give individuals more control over the construction of their identities. Knowing the possibility of incidental findings, the types of incidental findings that can be made, and the identity pressures these findings can pose can help individuals structure their life narratives in a way that provides the most coherence and meaning.

Of course, additional considerations are necessary. Consultation with neuroscientists and other qualified individuals who understand the limitations of fMRI research and the meaning of fMRI test results should be required prior to any use of fMRI outside the clinical and research contexts, especially because fMRI remains experimental in many of its uses. Scientists should consider their role in informing the public about the proper uses of fMRI and permissible interpretations of test results. And bioethicists, lawyers, and others should consider ways of exploring the ethical, legal, and social implications of advances in neuroimaging technology without contributing to technology hype.

Advances in science and technology frequently raise new ethical, legal, and social issues. Developments in neuroscience and neuroimaging technology are no exception. The potential of fMRI to reveal thoughts, characteristics, and social behaviors poses a significant challenge to existing confidentiality and privacy provisions, many of which were designed to protect health information. Identification of the considerable gaps in coverage can inform policy discussions about the need to protect confidentiality, privacy, and identity as attempts to transfer fMRI technology outside the research context are made.