

Incidental Findings: A Common Law Approach

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Abstract

Federal regulations governing human subjects research do not address key questions raised by incidental neuroimaging findings, including the scope of a researcher's disclosure with respect to the possibility of incidental findings and the question of whether a researcher has an affirmative legal duty to seek, detect and report incidental findings. The scope of researcher duties may, however, be mapped with reference to common law doctrine, including fiduciary, tort, contract and bailment theories of liability.

Introduction

Incidental findings may be defined as observations of potential clinical significance that are unexpectedly discovered in healthy subjects or patients recruited to brain imaging research studies and that are unrelated to the purpose or variables of the study (Illes et al., 2006). During the last ten years, several groups of scientists have examined the extent to which neuroimaging research reveals incidental arteriovenous malformations, brain tumors, developmental abnormalities, and other conditions in research participants (Vernooij et al., 2007). Current data suggests that 15 to 50% of asymptomatic research subjects have a brain anomaly, depending on age, and that findings are clinically significant in 2 to 8% of all asymptomatic subjects (Illes, 2006). Although subjects report that they expect research scans to detect abnormalities if they exist and that they want incidental findings communicated to them, procedures for handling incidental findings vary widely (Kirschen et al., 2006).

Incidental findings have drawn significant attention in the neuroethics literature (Illes, 2006; Illes, Kirschen, et al., 2004; Illes, Rosen, et al., 2004; Illes et al., 2006; Illes et al., 2008; Symposium, 2008). Much of the legal discussion involving incidental findings has appropriately been framed in terms of federal Common Rule requirements relating to the minimization of risks, the balancing of research risks and benefits, a description of the reasonably foreseeable risks and any benefits in the informed consent form, the monitoring of data, and the provision to the research participant of significant new findings that may affect the participant's willingness to continue in the study (45 C.F.R., 2007a-c). The Common Rule does not, however, directly address other key questions, including whether researchers have an obligation to look for incidental findings, the process that should be followed when a researcher suspects an incidental finding, the appropriateness of seeking a

consultation regarding an incidental finding, and the scope of disclosure to the research participant and her physician. The Common Rule also does not provide specific counsel regarding the best way to describe the possibility of incidental findings in the informed consent form, whether research participants may refuse to be told about incidental findings, the locus of financial responsibility for follow-up care, and the role of institutional review boards, funding agencies, and the government in guiding the answers to these questions (Wolf, 2008b). In the absence of federal direction, several groups of authors have carefully considered the ethical and legal concerns posed by incidental findings and have offered practical approaches for handling them (Heinemann et al., 2007; Illes et al, 2008; Wolf, 2008b), although a consensus has yet to emerge (Wolf, 2008a).

In this article, I would like to examine the issue of incidental findings in neuroimaging research from an American common law perspective. Can U.S. case law provide any additional guidance for institutions regarding how best to respond to incidental findings? Have any courts specifically addressed the scope of any duties that may apply to researchers in the context of incidental findings? If not, may the scope of any researcher duties be mapped with reference to fiduciary, tort, contract or entrustment theories of liability?

Incidental Findings Cases

A search in the combined Federal and State Cases database of LexisNexis, an electronic legal research system, reveals 180 American judicial opinions containing the phrase "incidental finding," most of which involve controversies unrelated to science or medicine. Additional searches using phrases such as "unanticipated findings," "unanticipated medical events," "unforeseen medical conditions," and "unforeseen medical problems" yield significantly more cases, although most are irrelevant. A few cases are, however, worthy of review and discussion.

In *Iacangelo v. Georgetown University*, Karen Kerris participated as a member of a control group in a neuroimaging study conducted at the National Institutes of Health (NIH), where she worked (Iacangelo, 2006). As part of the study, the investigators scanned Ms. Kerris' brain using magnetic resonance imaging (MRI) and discovered that she had a bithalamic arteriovenous malformation (AVM) that measured between six and seven centimeters in diameter. According to the judicial opinion, "Ms. Kerris was told that AVM was a terminal condition, and she was referred to Defendant Georgetown University for an angiogram" (*1). The passive language of the opinion does not clarify exactly who told Ms. Kerris about the existence of her incidental finding or that AVM was a terminal condition, although the opinion suggests that it may have been a member of the research team because the opinion had not yet identified anyone other than Ms. Kerris or the NIH. The opinion also does not describe the procedures that were followed for reviewing the participants' scans or contacting participants who had suspected incidental findings.

An angiogram conducted at Georgetown Hospital confirmed that Ms. Kerris had an "AVM of the highest grade of severity located deep within her brain." A few months later, a physician at Georgetown Hospital unsuccessfully treated Ms. Kerris with three different embolization procedures. By the time of the lawsuit, which stated multiple causes of action against the treating physician and Georgetown Hospital, Ms. Kerris' condition had deteriorated to the point where she required a guardian. One of the legal issues before the court was whether the treating physician was liable for medical malpractice and failure to obtain informed consent to treatment because he had used mixtures in the first embolization procedure (Histoacryl® and Lipiodol®) that were not approved for medical use in the U.S., one of which (Histoacryl®) was expressly contraindicated for use on the surface of the brain, in the nervous system, or in the blood vessels.

The defendants in the Iacangelo case included the treating physician and Georgetown Hospital. The plaintiffs did not name the NIH or any individual members of the research team as defendants, presumably because the plaintiffs could find no fault with the team's detection of the incidental finding or decision to refer Ms. Kerris to a hospital for treatment. Treating physicians who fail to detect potentially dangerous incidental findings in the clinical setting, on the other hand, have been named as defendants. In *Lo v. Burke*, a radiologist read a CT scan for a patient, Mary Burke, who had suspected liver disease (Lo, 1995). The radiologist failed to detect an incidental finding, which was an unrelated three-centimeter cyst on Ms. Burke's pancreas. Two years later, the radiologist read a second CT scan for Ms. Burke and observed a five-centimeter pancreatic cyst. As part of the radiologist's interpretation of the second scan, the radiologist reviewed the first scan again and observed the existence of the three-centimeter cyst, noting its subsequent growth in size. The radiologist subsequently reported the existence of the cyst, which was removed and determined to be malignant. The patient died from pancreatic cancer less than seven months after the second CT scan, and the executor of the patient's estate sued the radiologist for wrongful death.

One of the issues before the court was whether the radiologist's failure to detect the three-centimeter cyst in the first scan caused Ms. Burke's death. The plaintiff's expert witness, a general surgeon, testified that most pancreatic cysts are discovered when they measure five to six centimeters and that the first CT scan showing the three-centimeter cyst was "about as early as I have ever seen the detection of a pancreatic cyst done" (p. 313). The surgeon further testified that if the cyst had been removed shortly after the first CT scan, "no cancer could have later formed within the cyst to cause Ms. Burke's death" (p. 318). The court concluded that the surgeon's testimony provided the necessary causal link between the radiologist's negligence and Ms. Burke's death.

The Iacangelo and Lo cases involved defendant physicians who had treatment relationships with and primary duties of care to their patients. These cases did not involve defendant researchers whose stated goals included collecting data and creating generalizable knowledge. The Iacangelo and Lo holdings thus do not dictate that a researcher who fails to detect or report a potentially dangerous incidental finding on a research-grade scan will be held to the same standard of care as are radiologists or other physicians who read clinical-grade scans for specific patients in the inpatient or outpatient setting (Morreim, 2004). What these cases may suggest is that individuals whose conditions worsen and the survivors of individuals who die may seek to impose liability on: (1) the person who first reviewed the scan containing the incidental finding if earlier treatment would have yielded a better clinical outcome; or (2) a physician who subsequently and unsuccessfully treated the condition. Whether researchers have an independent and affirmative legal duty to seek, detect, and report incidental findings is discussed in more detail below.

Informed Consent and Scope of Disclosure Cases

Beyond case law that expressly refers to incidental findings, several well-known cases address more broadly the duties of researchers with respect to the scope of disclosure of research risks. In *Whitlock v. Duke University*, for example, Leonard Whitlock suffered organic brain damage after participating in a simulated deep dive experiment at Duke University (Whitlock, 1986). Mr. Whitlock subsequently sued Duke University and Dr. Bennett, the director of the relevant laboratory, for fraud, conspiracy to commit fraud, breach of fiduciary duty, intentional infliction of emotional distress, negligence, loss of consortium, breach of the Common Rule, strict liability for ultrahazardous activity, and strict liability for human experimentation. In his fraud claim, Mr. Whitlock alleged that Dr. Bennett intentionally failed to inform Mr. Whitlock of the danger of organic brain damage by not specifically listing organic brain damage as a risk on the consent form. Under North Carolina

law, a plaintiff claiming fraud must show: (1) the defendant made a representation to a material fact, (2) the representation was false, (3) the defendant knew the representation was false or made the representation recklessly without any knowledge of its truth, (4) the defendant made the false representation with the intention that it should be relied on by plaintiffs, (5) the plaintiffs reasonably relied upon the representation and acted upon it, and (6) the plaintiffs suffered injury. The court ultimately found that Mr. Whitlock, an experienced diver who signed and read the consent-to-research form that expressly advised him of the risks of death and disability as well as the experimental nature of the dive and the existence of "unknown risks," could not prevail on his fraud claim even though the consent form did not specifically list organic brain injury. The court reasoned that there was no evidence that Dr. Bennett knew of the specific risk of organic brain damage. Stated in terms of the fraud cause of action, Dr. Bennett did not falsely omit the risk of organic brain damage on the consent form.

In his negligence claim, Mr. Whitlock alleged that Dr. Bennett negligently failed to warn of the risk of organic brain injury. Negligence claims require duty, breach of that duty, actual and proximate cause, and compensable damages. In its examination of the first element of the negligence cause of action, the scope of the duty owed by Dr. Bennett to Mr. Whitlock, the Court relied on the Nuremberg Code, the Declaration of Helsinki, and the Common Rule to hold that a researcher has a duty to "make known to the subject all hazards reasonably to be expected and the possible effects upon the health and person of the subject" (p. 1471). The court also compared the strengths of the duties applicable to researchers engaged in nontherapeutic experiments and health care providers and found that researchers, not providers, have the higher duty of disclosure: "[T]he degree of required disclosure of risks is higher in the nontherapeutic context than required under [the North Carolina law applicable to health care providers, which only requires health care provider to "apprise the patient of the 'usual and most frequent risks and hazards' of the procedure"]" (p. 1471).

Applying these principles to the case before it, the court found that Dr. Bennett had a duty to inform Mr. Whitlock "of all risks that [we]re reasonably foreseeable" (p. 1471). Because Mr. Whitlock did not present any deposition, affidavit or other evidence showing that organic brain damage was a reasonably foreseeable risk, the court granted summary judgment to Dr. Bennett on Mr. Whitlock's negligence claim (as well as his conspiracy to commit fraud, breach of fiduciary duty, intentional infliction of emotional distress, loss of consortium, and breach of the Common Rule claims, which were based on the same factual allegations).

Can Whitlock and other similar judicial opinions provide any guidance to institutions regarding how best to disclose the possibility of incidental findings in informed consent conversations and forms? Most of the relevant cases address a researcher's duty to disclose a risk of injury, such as organic brain injury, that may be caused by an experimental drug, intervention, or other activity, such as simulated deep-sea diving. The issue in the incidental findings context is not the researcher's duty to disclose a risk of injury that may be caused by an MRI or other neuroimaging technology, such as a ferromagnetic injury. Instead, the issue is the researcher's duty to disclose the possibility that an unknown pre-existing condition might become known and that the condition might be potentially dangerous and require follow-up care. This distinction is important. Under general principles of tort law, individuals do not have a duty to warn of risks they did not create absent a special relationship or other exceptional circumstances. Whitlock and many of the other prominent informed consent cases thus are not exactly on point, although they are relevant to the extent they establish general rules relating to the scope of disclosure of research risks.

In its discussion of the plaintiff's fraud claim, Whitlock holds that a researcher who does not know of a particular research risk will not be liable for fraud for failing to disclose that risk. In its discussion of the plaintiff's negligence claim, Whitlock holds that a researcher has a

duty to disclose “all risks that are reasonably foreseeable,” not just the usual and most frequent risks (p. 1472). I suspect that future courts might focus on these aspects of Whitlock and, if presented with the issue, find that neuroimaging researchers have a duty to disclose not only the possibility of incidental findings but also the types of incidental findings that are reasonably foreseeable. The question thus becomes whether a particular incidental finding is reasonably foreseeable.

A number of studies published in the last decade in prominent scientific journals have examined the prevalence of incidental findings in neuroimaging studies. In one recent study examining the prevalence of incidental findings in 2,000 MRI research participants, the authors found asymptomatic brain infarcts, cerebral aneurysms, and benign primary tumors most frequently, but also one malignant primary brain tumor, one case of multiple cerebral metastases in a patient previously treated for lung cancer, one large, chronic subdural hematoma in a patient who had minor head trauma a month prior to the scan, and several cases of cavernous angioma, arachnoid cysts, type I Chiari malformations, major-vessel stenosis, dermoid cysts, and white matter lesions (Vernooij et al., 2007). A research participant seeking to impose a stringent duty of disclosure on a researcher might attempt to introduce these studies as evidence of the types of incidental findings that are reasonably foreseeable. Although a court likely would not impose a duty on a researcher to disclose the possibility of each and every type of incidental finding that has ever been detected in a reported neuroimaging study, a court might impose a duty with respect to particular incidental findings identified with some regularity in the scientific literature, reasoning that these findings are reasonably foreseeable.

In the absence of specific guidance regarding the legally required scope of disclosure, risk-averse institutions may feel pressured to disclose to prospective neuroimaging research participants as many potential incidental findings as possible, a result referred to as “over-disclosure” in other informed consent contexts. Some prospective participants subject to over-disclosure may be overwhelmed by the dozens of possible incidental findings and may be unable to focus on the meaning and import of the most likely or clinically significant findings. Other prospective participants may simply ignore the dozens of possible incidental findings if the relevant descriptions are too lengthy or legalistic. Until the law clarifies the appropriate scope of disclosure, researchers, institutional review boards, and legal counsel should work together in an attempt to balance the benefits and risks of disclosure and over-disclosure.

A Duty to Seek and Detect Incidental Findings?

The discussion above focused on the scope of a researcher’s disclosure with respect to the possibility of incidental findings. A second issue is whether a principal investigator or someone on his or her behalf has an affirmative legal duty to seek, detect and report incidental findings. This analysis is complicated not only by the absence of directly relevant case law, but also by the wide variety of settings in which neuroimaging research is conducted and the different education, training and experience of the individuals who conduct neuroimaging research. Some neuroimaging studies may be conducted within or adjacent to a hospital or medical center, while others may not. In some laboratories, students may be permitted to scan participants independently (Illes, Kirschen, et al., 2004), while in others, only senior members of the research team may scan participants. Students and investigators who conduct and participate in neuroimaging research may be training or trained in a wide variety of medical and nonmedical fields, including neurology, neurosurgery, radiology, neuroradiology, family practice, psychiatry, clinical psychology, experimental psychology, neuropsychology, neuroscience and even philosophy. Given the variety of neuroimaging research settings, personnel, and protocol, it is difficult to predict which legal duties courts will impose on particular research activities. It may be helpful,

however, to review the causes of action stated most frequently by participants against researchers and consider how these theories of liability may apply in the context of incidental findings.

During the last two decades, research participants have filed a number of lawsuits against researchers for physical and other injuries and deaths that occurred during or shortly after participation in cell line, gene therapy, cancer vaccine, bone marrow, and other experiments (Jansson, 2003; Morreim, 2004). Although none of these lawsuits involved a claim based on a neuroimaging researcher's failure to seek, detect or report an incidental finding, the plaintiffs in these cases have attempted to impose liability on researchers based on several different causes of action, including breach of fiduciary duty, negligence and breach of contract. The potential application of these theories of liability in the context of incidental findings follows.

Fiduciary Duties

A fiduciary relationship may be expressly or impliedly created (Greenberg, 2003). Because it is unlikely that many researchers expressly identify as fiduciaries vis-à-vis their participants, I will focus on implied fiduciary relationships. Implied fiduciary relationships are premised on the specific facts and circumstances surrounding the transaction and the relationship of the parties. These relationships have been found when confidence is reposed by one individual (the principal) and trust is accepted by the other individual (the fiduciary) (Greenberg, 2003). Implied fiduciary relationships are two-way relationships: The principal must have placed trust in the fiduciary and the fiduciary must have accepted that trust. Once the relationship is formed, the fiduciary has a duty to act with undivided loyalty in the best interests of the principal (Suthers, 2005). The fiduciary duty is extremely high, and courts carefully scrutinize transactions between fiduciaries and principals.

Courts have imposed fiduciary duties on trustees, corporate directors, partners, lawyers and financial planners, as well as some physicians who treat patients in the clinical setting. In the context of incidental findings, the threshold question would be whether neuroimaging researchers have a fiduciary relationship with their participants. A contingent question is whether a research participant could succeed in litigation against a research team or individual team member for breach of fiduciary duty based on the failure to seek, detect or report an incidental finding.

Research participants have sought to impose fiduciary duties on researchers in other research contexts, although usually unsuccessfully. In *Moore v. Regents of the University of California*, a patient (Moore) who underwent treatment for hairy-cell leukemia, and whose treating physician used the patient's cells to establish and patent a new cell line without his permission, sued the physician (Dr. Golde), the Regents of the University of California (Regents), a researcher employed by the Regents (Quan), and other parties for breach of fiduciary duty and twelve additional causes of action (Moore, 1990). The California Supreme Court applied the fiduciary duty to Dr. Golde, but summarily dismissed the breach of fiduciary cause of action with respect to the other defendants: "The Regents, Quan [and others] are not physicians. In contrast to Dr. Golde, none of these defendants stood in a fiduciary relationship with Moore or had the duty to obtain Moore's informed consent to medical procedures" (p. 133). By its express language, Moore left open the issue of whether a researcher involved in an informed consent process might have a fiduciary duty.

Other courts have dismissed breach-of-fiduciary-duty causes of action when the research participant failed to present sufficient evidence of the formation of the fiduciary relationship. In *Greenberg v. Miami Children's Hospital Research Institute*, the plaintiffs sued a researcher, hospital and research institute for breach of fiduciary duty based on the defendants' alleged failure to disclose material information relating to their disease research

(Greenberg, 2003). When the defendants argued that the plaintiffs failed to allege any facts showing that the defendants had recognized or accepted the trust, as required to form the fiduciary relationship, the plaintiffs responded by alleging that the defendants impliedly accepted the trust by undertaking research that they represented as being for the benefit of the plaintiffs. The court disagreed, reasoning that the plaintiffs had not sufficiently alleged the second element of a fiduciary relationship – acceptance of trust by the researchers – and that this element cannot be assumed from the subjects' research participation: "There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given" (p. 1072).

Other courts also have considered, at least in dicta, the question of whether researchers owe their participants fiduciary duties. *Suthers v. Martin* involved an investigation of an experimental Parkinson's treatment – glial-derived neurotrophic factor (GDNF) – at several sites, including New York University (NYU) (Suthers, 2005, 2006). Amgen, the trial sponsor, discontinued the trials after data indicated that GDNF was neither safe nor effective. Two of the research participants who received GDNF in an extended version of the study conducted at NYU sued Amgen to compel the provision of GDNF, which the participants believed relieved their Parkinson's symptoms. One of their causes of action was breach of fiduciary duty, which the court refused to impose on Amgen: "[T]here is no basis in fact or law to impose a fiduciary duty running from the sponsor of an independent study to participants who it does not select, has not met, and about whom it may not know the details of their medical conditions" (p. 429). Because the participants did not name NYU or its researchers as defendants, the court did not address the applicability of the fiduciary duty to the research team, although the court noted in dicta one bioethicist's criticism of the application of fiduciary duties to researchers.

Notwithstanding these cases, the nature of the relationship between researchers and participants continues to be debated. Some plaintiffs' lawyers argue that researchers are fiduciaries vis-à-vis their participants. Attorney Alan Milstein, who successfully represented University of Pennsylvania gene therapy participant (and decedent) Jesse Gelsinger, recently stated:

Once the research subject [. . .] signs the informed consent document, a fiduciary relationship is formed between the [principal investigator] and the research subject. The very nature of scientific research on human subjects creates special relationships out of which fiduciary duties arise, similar to the physician/patient relationship. The fiduciary relationship is formed not only by the informed consent agreement between the parties, but also by the trust the subject necessarily places in the researcher (Milstein, 2008).

Milstein believes that neuroimaging researchers' fiduciary duties require a clinical-like review of neuroimages by qualified personnel and that the "Good Samaritan Approach," in which researchers tell their prospective participants that scans are not clinical quality and will not be reviewed by qualified medical personnel, would constitute a breach of the fiduciary duty.

Other attorneys and scholars take a middle ground and admit that there are important distinctions between the researcher-participant relationship and the types of relationships traditionally governed by fiduciary principles, although they use the concept of the fiduciary relationship as a framework for thinking about the researcher-participant relationship (Coleman, 2005). Finally, some attorneys and scholars expressly oppose the application of fiduciary duties to researchers, reasoning that the relationship between researcher and participant differs fundamentally from that between physician and patient, that clinical

research should not be conflated with medical care, and that the purpose of research is not to benefit individuals (Heinemann et al., 2007).

A hypothetical or two may be used to illustrate the debate regarding the nature of the researcher–participant relationship in the context of incidental findings. First, consider a nonphysician neuroimaging researcher who conducts and reviews a low-quality research-grade scan, fails to detect a small AVM, and therefore has a participant who does not know to seek treatment that could improve the participant’s clinical outcome. (Also assume that the researcher accepted no responsibility for reviewing the scan for incidental findings in the informed consent documentation or other conversations with the participants.) Could the participant or his or her survivors successfully argue that the researcher stood in a fiduciary relationship with the participant and breached that duty by failing to detect and report the AVM?

Second, consider a research team that is composed mostly of nonphysician researchers but that hires or contracts with a diagnostic neuroradiologist for the sole purpose of reviewing all of the scans for incidental findings to see which participants may require follow-up treatment. Now assume that the neuroradiologist fails to detect an incidental finding. Should a fiduciary duty be imposed on the neuroradiologist or research team? If so, was there a breach of that duty when the neuroradiologist failed to detect and report the incidental finding?

Relying on the principles stated in Moore, Greenberg, and Suthers, I suspect that a court may find insufficient evidence of the formation of the fiduciary relationship in the first hypothetical because there is no evidence that the researcher expressly or impliedly accepted the participant’s trust with respect to incidental findings. In addition, the relevant case law discourages courts from assuming the existence of the trust. The catch in the second hypothetical is that a plaintiff’s lawyer may point to the research team’s decision to hire the diagnostic neuroradiologist as evidence of the research team’s acceptance of trust with respect to incidental findings. This evidence may assist the plaintiff’s lawyer in surviving a motion to dismiss or summary judgment on the breach of fiduciary claim, although it is unclear how the court ultimately would characterize the nature of the researcher–participant relationship, especially given the availability of tort and other duties that may be more appropriate.

Tort and Other Unspecified Duties

In a torts case based on negligence, a plaintiff will prevail if she can prove a duty, a breach of that duty, actual and proximate cause, and compensable damages. Courts have applied duties sounding in tort to researchers before. In *Grimes v. Kennedy Krieger Institute*, the court considered two separate negligence actions involving children who allegedly developed elevated levels of lead dust in their blood while participating in a research study (Grimes, 2001). The court held that, “special relationships, out of which duties arise, the breach of which can constitute negligence, can result from the relationships between researcher and research subjects” (p. 846). Perhaps because Grimes and other cases do not provide much detail regarding the potential application of tort duties to researchers, the application of these duties continues to be debated. For example, Heinemann et al. (2007) suggest that researchers have a duty to “carefully inspect [. . .] and interpret [. . .]” neuroimages according to “accepted scientific criteria,” but reason that no higher duty applies because the purpose of the research study is not the diagnosis of disease in individual patients (p. 1985).

Given the frequency with which negligence causes of action have been stated against researchers in the past, I do anticipate that tort duties may play a role in the resolution of future cases that may arise in the context of incidental findings. Again, the threshold

question would be whether a court would find that the standard of care requires neuroimaging researchers to seek and detect incidental findings. Courts sometimes look to evidence of industry custom for guidance regarding the applicable standard of care. While the NIH gives full clinical brain scans to every intramural neuroimaging study participant, other neuroimaging research teams do not. The industry custom with respect to incidental findings, at least outside the NIH, is thus unclear.

If a court did impose tort duties on a neuroimaging researcher, the second question would be whether the researcher breached those tort duties. In addition to allegations regarding the failure to seek or detect incidental findings, the timing of any disclosures that are (not) made to the participant may be relevant to the existence of a breach. In *Grimes*, for example, the court emphasized that the researchers should have disclosed the elevated lead blood levels to the participants in a timely manner, not at the conclusion of the study: "This duty [. . .] requires the researcher to completely and promptly inform the subjects of potential hazards [. . .]" (p. 843). *Grimes* suggests that neuroimaging researchers should promptly inform their participants of suspected incidental findings. Although *Grimes* does not identify the exact time frame in which disclosure should occur, the opinion suggests that the disclosure should neither be unreasonably delayed nor postponed until the conclusion of the study.

Contract Duties

A somewhat more straightforward duty for a court to apply is a contract duty. Over the last ten years, several groups of research participants have sued researchers for breach of duties set forth in research-related documents. In *Grimes*, the court held that consent forms in nontherapeutic research projects could, under certain circumstances, constitute contracts (p. 858). *Suthers* also considered whether consent forms can constitute contracts and stated in dicta that they may establish participant rights vis-à-vis researchers (pp. 424–425; 427).

Assuming that a contract exists, the researcher would be required to perform the obligations set forth in the contract or pay damages for failure to perform. The scope of the researcher's contractual obligations would depend on the terms of the contract. For example, if a consent form that constituted a contract stated that, "Every scan will be reviewed by a research team member who is a diagnostic neuroradiologist and who has been trained to detect potentially dangerous incidental findings and report them immediately to the participant to enable early diagnosis and improve clinical outcomes," a participant whose incidental finding went undetected may have a relatively easy breach of contract case. On the other hand, I suspect that a participant would have greater difficulty proving breach of contract if the consent form stated that, "(1) the brain scanning is for research purposes only; (2) the brain scanning is not directed toward, or designed for, clinical diagnosis; (3) the research team members are not trained in diagnostic radiology; and (4) the research-grade scans are not optimized to find brain abnormalities." The extent to which research consent forms are structured with an eye towards legal risk management usually depends on the institution and may change as researchers are sued for breach of contract more frequently and as institutions become more risk averse. Case law such as *Grimes* makes clear, however, that a researcher cannot waive his or her other duties (whether they be characterized as tort, fiduciary, or other unspecified duties) through exculpatory language embedded in a contract: "A researcher's duty is not created by, or extinguished by, the consent of a research subject or IRB approval. The duty to a vulnerable research subject is independent of consent [. . .]" (p. 858).

Breach of Limited Entrustment

Scholars are beginning to consider alternative theories of liability that may apply to neuroimaging researchers. One theory that does not yet appear in the case law but has been suggested by scholars is a theory of partial or limited entrustment, or bailment (Belsky and Richardson, 2004; Richardson, 2008; Richardson and Belsky, 2004). Under the common law, bailment is a legal relationship in which physical possession of personal property is transferred from one person (the bailor) to another person (the bailee), who subsequently holds possession of the property for a specific purpose. The bailee returns possession of the property to the bailor when the purpose of the transfer has been accomplished. In addition to completing the service(s) for which transfer of possession is required, bailees also have a duty of care with respect to the subject matter of the bailment. In the classic bailment transaction involving an automobile temporarily transferred by its owner to a mechanic for repair, the mechanic also may be responsible for rescuing the automobile from a fire that unexpectedly occurs next door.

Some scholars have suggested that the concept of bailment may be a useful framework for considering whether neuroimaging research participants have entrusted an aspect of their health to researchers (Belsky and Richardson, 2004; Richardson and Belsky, 2004). In the context of incidental findings, some scholars have suggested that research participants have partially and limitedly entrusted neuroimaging researchers with certain aspects of their health, and that diagnostic review of participant scans may be within the scope of that entrustment (Richardson and Belsky, 2004). Other scholars have criticized the application of the entrustment theory to neuroimaging research, reasoning that clinical research does not aim to promote the health of research subjects (Miller et al., 2008).

The possibility that future research participants may raise a limited entrustment theory of liability is not out of the question due to the frequency with which plaintiffs have made bailment claims in clinical and other related health care contexts. An infertile couple whose embryologist dropped a tray of nine fertilized eggs, destroying eight of them, stated a bailment claim in their petition (*Institute for Women's Health v. Imad*, 2006); likewise, plaintiffs whose deceased kins' organs and tissues were removed without consent and were sold for transplant, research and medical education also have stated bailment causes of action (Andrews, 2006). Whether a future court would consider an individual's decision to participate in neuroimaging research a bailment transaction is unclear and likely would require a court to engage in several different lines of analysis, including whether a participant's health constitutes transferable personal property (and, if not, whether the object of transfer must constitute personal property), as well as any reasons that may support the extension of the bailment theory to neuroimaging research. Reasons that have been offered in support of the extension of the bailment theory to neuroimaging research include the participant's waiver of his or her normal rights as a condition of participating in the research, the research team's superior knowledge in terms of understanding the clinical significance of suspected incidental findings, and the need for some researcher discretion, given the difficulty associated with disclosing to future participants each and every possible incidental finding and establishing a mutually agreed upon notification and referral process for each incidental finding (Richardson and Belsky, 2004).

If a court allowed the application of the theory of bailment to neuroimaging research, a follow-up question would be whether the defendant researcher as bailee satisfied his or her duty with respect to the participant's health. In traditional bailment transactions, the scope of the bailee's duty varies, depending on who benefits from the bailment (Melly, 2007). A bailee may be required to exercise ordinary and reasonable care if the bailment is for the mutual benefit of the parties; great care if the bailment is for the sole benefit of the bailee; and slight (or less than ordinary and reasonable) care if the bailment is for the sole benefit

of the bailor (Melly, 2007). The scope of the bailee's duty also depends on the express or implied terms of any bailment contract (Melly, 2007).

Applying these principles to a standard neuroimaging research protocol involving a healthy participant who is not expected to benefit from scanning and a researcher who is expected to benefit from the collection of the participants' data, a court might find that a neuroimaging researcher has a duty that falls somewhere between ordinary and reasonable care and great care. Informed consent or other "bailment" documentation that states that the research team will seek, detect and report incidental findings, or that suggests that the research protocol is designed and the research team is trained to seek and detect anomalies, may further support the imposition of a nonminimal duty. I suspect that consent conversation and documentation that clearly informs the participant that the research protocol is not designed and the research team is not trained to seek or detect anomalies may have the opposite effect.

Conclusion

Much of the legal discussion involving incidental findings has appropriately been framed in terms of federal Common Rule requirements, but the common law can provide additional guidance with respect to the scope of duties when federal standards are necessarily vague. Although U.S. common law does not specifically address the duties of American researchers with respect to incidental findings, the scope of researcher duties may be mapped with reference to fiduciary, tort, contract and bailment theories of liability.

Although I expect future plaintiffs to bring claims against researchers based on all four theories of liability, I anticipate that plaintiffs may have some success in either or both contract- and negligence-based lawsuits when the research team includes an individual, such as a neuroradiologist, who is trained to seek and detect brain anomalies, the research protocol states that the duty or role of this individual is to provide diagnostic review of participant scans, and the individual fails to review a scan or fails to detect an anomaly listed in the informed consent documentation (for breach of contract obligations) or that a reasonably prudent neuroradiologist would have detected in the same or similar circumstances (for breach of tort duties). On the other hand, participants may have difficulty proving breach of contract duties in cases in which participants are informed that the brain scans provided are for research purposes only; the brain scanning is not directed toward, or designed for, clinical diagnosis; the research team members are not trained in diagnostic radiology; and the research-grade scans are not optimized to find brain abnormalities.

I suspect that future courts will hesitate to apply fiduciary duties to researchers whose goals include the collection of data, the creation of generalizable knowledge, or other goals that may conflict with the best interests of the participants, as well as bailment theories of liability, which courts may find too novel, at least initially, to apply outside the context of traditionally transferred personal property. Given the increasing number of lawsuits filed by participants and their families against researchers, as well as the number of lawsuits that contain fiduciary and other novel claims, however, the application of these theories of liability in the context of incidental findings must be continually monitored and assessed.

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