

## **A Private Right of Action for Informed Consent in Research**

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## INTRODUCTION

Imagine your doctor tells you that a procedure involving removal of spinal fluid is necessary to diagnose your recurring headaches. He does not tell you—nor do you inquire about—the risks involved in the intervention, which include a very small risk of permanent partial paralysis. Unfortunately, paralysis occurs. American courts have established a rule of consent that provides that the physician has an affirmative duty to disclose the material risks inherent in the proposed therapeutic treatment or surgery.<sup>1</sup> Thus, among other claims, you have a common law right to recover against the physician for failure to provide adequate informed consent.

Now imagine that, instead of seeking care from your physician, you have decided to become a participant in a research protocol that is intended to study the cause of recurring headaches. During the process of enrolling you in the study, the investigator does not tell you—nor do you inquire about—the risk of permanent partial paralysis. Again, unfortunately, paralysis occurs. Although the law governing human subjects research might lead the investigator to lose funding, no equivalent private right of action exists in the research context, and thus you are unlikely to be able to seek damages for the investigator's failure to provide adequate informed consent.

Finally, consider a complicating detail to the latter scenario: the investigator, in the course of the study, runs a test on a biological sample that he removed during the procedure in order to study a hypothetical correlation between the headaches and a certain genetic defect. He discovers, incidentally, that you carry a gene that predisposes you to Alzheimer's Disease. Although no law requires the investigator to tell you this information, there is an emerging general consensus that the investigator has an obligation to disclose such findings (or at least the possibility of such findings) to you, which could also potentially enable you to seek damages where the investigator fails to make the appropriate disclosures.

That a patient who is harmed by her doctor due to lack of informed consent has a right to recover is an established tenet of tort law. However, for historic reasons,<sup>2</sup> such a right does not extend to a research participant<sup>3</sup> who is harmed due to a lack of informed consent

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<sup>1</sup> See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

<sup>2</sup> See *infra* Part I.A.

<sup>3</sup> Traditionally, the term "subject" has been used to describe individuals who enrolled in research protocols, and the federal regulations (the Common Rule and FDA regulations) employ that term. More recently, commentators have begun to use the term "participant" "in order to 'reinforce the aspiration to involve participants

by the investigator in a research protocol. This distinction between the rights of certain individuals to seek remedies directly from those who neglected to communicate the risks of an intervention has been the subject of extensive literature on the doctrine of informed consent,<sup>4</sup> although courts have generally been either unwilling or unable to extend a private right of action to research subjects.

Significantly, however, the typical research model has evolved since the most notable court efforts to find a duty of care, premised on a special relationship<sup>5</sup> between the investigator and research participant. In contrast to research protocols that required more involved medical interventions, protocols that require minimally invasive procedures—e.g., a simple blood draw for a genetic test or the use of magnetic resonance imaging (MRI)—are much more the norm today. Further, with almost daily genetic and medical discoveries, there is an ever-increasing possibility of finding out information about the research participant that is beyond the scope of the protocol. Thus, this Article proposes that the emergence of genetic testing technologies, the proliferation of research involving biological samples, and the escalating use of medical imaging<sup>6</sup> may further transform the relationship between the investigator and research participant.

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more directly in research and its oversight.” Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 388 n.1 (2005) (citing Comm. on Assessing the Sys. for Prot. Human Research Subjects, Inst. of Med., *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs* 34 (2001)). Because of their common and frequent usage, this Article uses the terms “subject” and “participant” interchangeably, although each term carries with it particular meaning and significance.

<sup>4</sup> See generally JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* (Oxford Univ. Press, 2001); see also generally E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL’Y 1, 63 (2003); Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANN. INTERN. MED. 40, 40 (2003); Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229 (2003); Elizabeth R. Pike, *Recovering from Research: a No-Fault Proposal to Compensate Injured Research Participants*, 38 AM. J. L. & MED. 7 (2012).

<sup>5</sup> See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

<sup>6</sup> PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, *ANTICIPATE AND COMMUNICATE: ETHICAL MANAGEMENT OF INCIDENTAL AND SECONDARY FINDINGS IN THE CLINICAL, RESEARCH, AND DIRECT-TO-CONSUMER CONTEXTS* 39 (Dec. 2013), available at [http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate\\_PCSBI\\_0.pdf](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf) (“Medical imaging—a modality that includes magnetic resonance imaging (MRI), computed tomography (CT) scans, X-rays, neuroimaging, and ultrasounds, along with techniques such as electroencephalography and electrocardiography that give rise to data capable of being represented as images—can lead to incidental and secondary findings.”).

The right to recover for lack of informed consent is premised on the duty that arises out of the relationship between the discloser and the discloser, which is grounded in the principle of autonomy. In the treatment context, when physicians fail to inform their patients about the risks of an intervention, patients who are then harmed by the undisclosed risks have recourse to a private right of action based in common law—a claim based on the failure to provide informed consent.<sup>7</sup> At its foundation, this recourse is based on the primacy of the doctor-patient relationship and arises out of the provider's duty to the patient. Breach of that duty—through failure to disclose information material to the patient's decision to pursue treatment—allows the patient to recover damages.

In contrast, research subjects who are harmed by medical research have no such right of action. The most significant federal regulation related to human subjects research, the Common Rule, includes no private right of action for participants who are harmed as a result of investigators' failure to disclose the risks of the research; instead, the penalty for violation of the regulations is typically loss of federal funding or suspension of the research. The lack of a private right of action for research harms is often attributed to the absence of a legally recognized relationship between the investigator and the participant. Consequently, this Article focuses on one element of tort liability—the duty of care—because of its centrality to the doctrine of informed consent and the principle of autonomy that it seeks to protect. Arguments for informed consent in both the treatment and research contexts, as well as for disclosure of incidental or secondary findings, are premised on the autonomy principle.

The evolution in the relationship between investigator and participant demonstrates the increasing need for a private right of action for failure to provide informed consent to research. Central to the contention of this Article, the emerging consensus that investigators have some obligation to disclose research findings<sup>8</sup> to

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<sup>7</sup> BERG ET AL., *supra* note 4, at 258 (“By granting patients access to the courts for independent review of their care, society provides a means of compensating patients who have suffered harms resulting from negligent practices, and of deterring physicians from engaging in such practices.”).

<sup>8</sup> In attempting to address the definitional confusion that has arisen in attempting to determine the extent of a researcher's obligation to return secondary and other research findings, Lisa Eckstein and colleagues have endeavored to suggest which definitions and conceptualizations are most appropriate to use in future disclosure frameworks. Lisa Eckstein, Jeremy R. Garrett & Benjamin E. Berkman, *A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings*, 42 J. L. MED. & ETHICS 190 (2014). For purposes of this Article, the authors' definition of “research finding”—“a new piece of information that relates to a particular individual discovered

research participants reflects an appropriate response to the changing nature of the investigator-research participant relationship, rendering it more like the doctor-patient relationship. The emerging expectation that an investigator should disclose (or offer the research participant the opportunity to receive) findings that are *secondary* to the research protocol—potentially accompanied by the associated private right of action for failure to do so—makes the lack of obligation to disclose the *primary* risks of the research protocol itself (and the lack of direct recourse for failure to do so), even more obvious and challenging. Thus, this Article proposes that the ethical duty to disclose research findings represents a shift in the relationship between the investigator and research participant, which therefore supports a private right of action for research participants, who, like patients, are harmed by the failure to provide informed consent. However, the standard of care for such a private right of action for research need not—and probably should not—absolutely mirror the standard of care owed to patients in the clinical setting.

Part I of this Article explores the evolution of, and justification for, a private right of action for harms that occur due to failure to provide informed consent in the treatment environment but not the research setting. Part II then addresses the evolving research model and, in particular, the investigator-participant relationship generally, with a focus on the central principle of autonomy. The Article then turns, in Part III, to the subject of returning or disclosing research findings in research involving imaging and the testing of genetic and biological samples. Finally, Part IV recommends a modified approach to extending the common law claim for lack of informed consent to the research setting.

## I. A PRIVATE RIGHT OF ACTION FOR TREATMENT BUT NOT RESEARCH

### A. *Informed Consent to Treatment*

To understand the common law right of action for failure to provide informed consent to treatment, one must look to its history. In most states, this negligence-based tort stands in contrast to the intentional tort of battery.<sup>9</sup> The prototypical battery case involves

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by virtue of research procedures”—is a particularly useful “catchall” for the incidental and secondary findings discussed here. *Id.* at 200.

<sup>9</sup> *Cobbs v. Grant*, 8 Cal. 3d 229 (1972); *Kennis v. Mercy Hosp. Med. Ctr.*, 491 N.W.2d 161 (Iowa 1992); *Mole v. Jutton*, 846 A.2d 1035 (Md. Ct. App. 2004); *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73 (2002); *Jaskoviak v. Gruver*, 638 N.W.2d 1 (N.D. 2002); *Messina v. Matarasso*, 284 A.D.2d 32 (N.Y.A.D. 2001); *Blanchard v. Kellum*, 975 S.W.2d 522 (Tenn. 1998). *But see* *Montgomery v. Bazaz-*

intentional unauthorized physical contact with a patient where the contact causes harm.<sup>10</sup> However, a patient can recover for battery even if she is not harmed, if the physician performs the intervention without the patient's knowledge or agreement.<sup>11</sup> Importantly, battery "assumes that important medical decisions are implemented through actual physical touching."<sup>12</sup> Today, battery is invoked at a less frequent rate than it was historically,<sup>13</sup> perhaps because treatment is often conducted with less physical touching due to the increasing use of noninvasive tests and procedures.

Over the course of the twentieth century, the medical profession shifted from a patriarchal system—in which the doctor held all the information and yielded all decision-making power within the doctor-patient relationship—to a more "patient-centered approach to health care,"<sup>14</sup> based on the ascension of the principle of patient autonomy within the doctor-patient relationship. Early references to the emerging doctrine of informed consent appeared toward the beginning of the twentieth century. In the seminal decision *Schloendorff v. Society of New York Hospital*, which revolved around

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Sehgal, 568 Pa. 574 (2002) (treating both no consent and lack of informed consent as battery claims). See also DOBBS' LAW OF TORTS, § 308 (2d ed. West 2014) ("The negligence in the informed consent claim is not negligence in performing a medical procedure, but rather negligence in failing to explain its risks, alternatives, and other related information.").

<sup>10</sup> DOBBS' LAW OF TORTS, § 33 (2d ed. West 2014).

<sup>11</sup> *Id.*

<sup>12</sup> Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 229 (1985).

<sup>13</sup> Jerry Menikoff, LAW AND BIOETHICS 156 (2001) ("[T]he tort of battery plays a relatively minor role in modern doctor-patient relations."). In INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 136 (Oxford Univ. Press, 2001), *supra* note 4, Jessica W. Berg et al. state:

By the mid-1970s, almost all states that had considered the question had concluded that inadequate disclosure is actionable only as professional negligence, not battery. . . . At the same time, the administration of therapy without any consent at all, or outside the scope of the consent given, is still actionable as a battery in many states.

Mark A. Rothstein & Gil Siegel, *Health Information Technology and Physicians' Duty to Notify Patients of New Medical Developments*, 12 HOUS. J. HEALTH L. & POL'Y 93, 121 (2012).

<sup>14</sup> Felicity Goodyear-Smith & Stephen Buetow, *Power Issues in the Doctor-Patient Relationship*, 9 HEALTH CARE ANALYSIS 449, 450 (2001). See also JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984); DAVID ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISIONMAKING (1991) (noting the increasing social distance between patients and physicians). But see Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician-Patient Relationship*, in READINGS IN HEALTH CARE ETHICS 12 (2002) ("Over the last few decades, the discourse regarding the physician-patient relationship has focused on two extremes: autonomy and paternalism. Many have attacked physicians as paternalistic urging the empowerment of patients to control their own care.").

allegations of unauthorized surgery during a routine examination, Justice Cardozo stated, “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable for damages.”<sup>15</sup> Although this language appears to establish the right of informed consent to treatment, the controversy in *Schloendorff* was not about the nature or amount of information the physician communicated to the patient as part of the patient’s consent to treatment. Instead, the case was based on the patient’s explicit *refusal* to consent to a specific surgical procedure.<sup>16</sup> Regardless, Justice Cardozo’s famous words represent the principal limitation on the physician-patient relationship.

The doctrine of informed consent developed via the common law under the rubric of negligence law, beginning in the 1950’s,<sup>17</sup> and an affirmative duty to disclose was first addressed in the courts in 1957.<sup>18</sup> Particularly in the 1960’s and 1970’s, patients began asserting increasing self-determination in their medical decision-making; this shift away from medical paternalism and toward patient-driven medicine has been described as “the historical transition from the regime of ‘doctor is right’ to ‘patient has rights.’”<sup>19</sup> Patient

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<sup>15</sup> 105 N.E. 92, 93 (N.Y. 1914).

<sup>16</sup> *Id.*; Menikoff, *supra* note 13, at 156. Thus, “[w]hen Cardozo talks about performing an operation ‘without consent,’ he is not referring to a failure to adequately explain the risks and benefits of the procedure. Rather, battery takes place only when something happens to a patient other than what the patient expected.” *Id.* In *Medical Research Litigation and Malpractice Tort Doctrines*, *supra* note 4, at 63, E. Haavi Morreim writes:

For research undertaken during the current era of federal supervision and mandatory informed consent, the most prevalent complaints concern inadequate, not absent, information. If battery applies to a complete failure to disclose, breach of informed consent would apply when a researcher has openly invited someone to enter a research protocol but insufficiently described its nature, uncertainties, risks or alternatives.

<sup>17</sup> Menikoff, *supra* note 13, at 157.

<sup>18</sup> *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170 (Cal. Ct. App. 1957) (holding that physicians had a duty to disclose all facts that were necessary for the patient to make an intelligent health care decision). Commentators have noted that the law’s focus on “psychic integrity has existed for almost as long [as the law’s concern for bodily integrity] and has received increasing support in this century as evidenced by the cases recognizing causes of action in tort law for intentional, and more recently, negligent infliction of emotional distress.” BERG ET AL., *supra* note 4, at 43.

<sup>19</sup> Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor is Right” to “Patient has Rights,”* 50 SYRACUSE L. REV. 1243 (2000). See also Azgad Gold, *Physicians’ “Rights of Conscience”—Beyond Politics*, 38 J.L. MED. & ETHICS 134, 135 (2010) (“[The doctor-patient relationship] has changed significantly as a direct result from the rise of the informed

empowerment means the ability to make fully informed decisions, based on adequate information furnished by one's physician, rather than relying on one's physician to know and decide what is best for the patient.<sup>20</sup> Because "courts were far more reluctant to characterize as batteries treatments or operations that were performed with the patient's consent but without an adequate disclosure by the surgeon of the risks, benefits, and alternatives to the agreed upon procedure,"<sup>21</sup> they turned to the doctrine of informed consent to remedy such harms.<sup>22</sup>

As a result, in order to ensure that the patient receives sufficient information with which to make a decision to undergo a specific treatment, courts turned to a negligence theory premised on the doctrine of informed consent.<sup>23</sup> Under this cause of action, failure to disclose the risks of an intervention may allow an individual to recover for harm arising from nondisclosure of information material to the individual's decision to agree to the intervention. In other words, a patient may claim lack of informed consent when she consented to the intervention itself but disclosure of the risks was insufficient. Thus, by allowing patients to recover for lack of *informed* consent—rather than just consent—courts have attempted to fill an important gap.<sup>24</sup>

Today, all United States jurisdictions have adopted some form of the doctrine of informed consent either by statutory enactment or judicial decision.<sup>25</sup> Until 1972, the question of the legal adequacy of a

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consent doctrine whose goals were the 'protection of patient or subject welfare and the promotion of autonomy.'). Gold identifies the legal transition to the doctor-patient relationship in the past four decades, in which "the informed consent process was established as a legal standard of care which enabled the patient to act as an autonomous 'persona,' according to her own wishes and values." *Id.* See also Leonard J. Long, *Can Health Care Conscientious Objectors Thread the Needle?*, 13 QUINNIPIAC HEALTH L.J. 51, 67–68 (2009).

<sup>20</sup> Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 318 (2002).

<sup>21</sup> *Id.* at 319.

<sup>22</sup> Although it is true that patients now have much more access to information "on the Internet, commercials, and television medical dramas," concern still exists about the quality of this information. Long, *supra* note 19, at 67–68. Thus, information furnished from one's own physician is likely to be the most accurate, personal, and reliable.

<sup>23</sup> BERG ET AL., *supra* note 4, at 134.

<sup>24</sup> The court in *Duncan v. Scottsdale Med. Imaging, Ltd.*, 70 P.3d 435, 439 (Ariz. 2003) addressed the distinction between lack of "consent" and lack of "informed consent," noting that "'lack of informed consent,' . . . should be pled in negligence, and 'lack of consent,' should be pled in battery." See also Menikoff, *supra* note 13, at 156–57.

<sup>25</sup> BERG ET AL., *supra* note 4, at 42–43. Most informed consent statutes were enacted after 1975. In general, jurisdictions where the doctrine of informed consent



patient's consent to medical treatment was most often raised when there were allegations that the consent was vitiated by the kind of medical treatment provided. Consent was invalid if a patient was not told that the procedure consented to was radically experimental or if the common presumptions of patient and physician were contradicted by the facts.<sup>26</sup> Thus, before 1972, consent was generally legally adequate as long as the patient had notice of the nature and scope of the proposed medical intervention: what the physician proposed and its probable result. The change was first announced in the cases *Canterbury v. Spence*<sup>27</sup> and *Cobbs v. Grant*,<sup>28</sup> in which both courts imposed a duty on the physician to tell the patient of the potential risks and benefits of the proposed treatment, the potential risks and benefits of alternative treatments, and the risks involved in refusing any treatment at all.<sup>29</sup> The purposes behind the doctrine of informed consent are several, and include protection of individual autonomy and dignity, avoidance of patient fraud or duress, encouragement of physicians to make good decisions, enablement of patient rational decision-making, and involvement of the public in medicine, via a policy of shared decision-making.

A claim of lack of informed consent requires the same elements required to establish a traditional negligence claim: (1) a duty of care owed by the defendant to use reasonable care to prevent harm to the plaintiff, (2) breach of that duty, (3) harm or injury to the plaintiff, and (4) a causal link between the injury and the breach of duty.<sup>30</sup> At the heart of this Article is the first element: the duty owed to the individual who is harmed due to the physical intervention. The traditional negligence requirements include an established physician-patient relationship, which imposes a physician duty of care. Such a relationship is sometimes characterized as a contractual one<sup>31</sup> in which

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has been introduced by common law decision have more extensive requirements concerning patient information and participation.

<sup>26</sup> *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

<sup>27</sup> *Id.*

<sup>28</sup> 8 Cal. 3d 229 (1972) (holding that a physician is under a duty to disclose to a patient those risks and benefits of the proposed treatment, alternative treatments, and of no treatment, which a hypothetical reasonable patient would consider material).

<sup>29</sup> BERG ET AL., *supra* note 4, at 136–37.

<sup>30</sup> BERG ET AL., *supra* note 4, at 133–34; Diane E. Hoffmann & Karen H. Rothenberg, *Whose Duty Is It Anyway?: The Kennedy Krieger Opinion and Its Implications for Public Health Research*, 6 J. HEALTH CARE L. & POL'Y 109 (2002); *but see* Susan M. Wolf, Jordan Paradise & Charlisse Caga-Anan, *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361 (2008).

<sup>31</sup> Richard Epstein, *Medical Malpractice: The Case for Contract*, 1 AM. BAR FOUND. J. 87, 127 (1976) ("The root problem with the informed consent doctrine is that it is

the patient knowingly and voluntarily seeks the professional assistance of the physician, thereby initiating the relationship, and the physician knowingly agrees to treat the patient.<sup>32</sup> The physician's goal in the relationship is to benefit the patient, either through treatment or preventative care. To demonstrate the existence of a doctor-patient relationship, courts typically require: (1) a direct connection between the doctor and patient, (2) that the patient sought care from the doctor, (3) the doctor's consent to render advice, and (4) the patient's reliance on the doctor's care.<sup>33</sup> A patient may not recover for lack of informed consent for nondisclosure of the risks of a proposed treatment if there is no doctor-patient relationship. The doctor-patient relationship is essential to a claim for failure to provide informed consent because of the inherent information disparity: the patient lacks the professional knowledge of the physician and is the one at risk of injury, illness, and death.<sup>34</sup> The professional can inform or advise the patient about the medical risks and benefits of an intervention.

Under the doctrine of informed consent, the physician must disclose the risks of the intervention and obtain consent before initiating treatment.<sup>35</sup> Thus, it focuses primarily on the duty of the physician to *disclose* information to the patient, and secondarily on the patient's *consent*. An individual claiming lack of informed consent must demonstrate that the physician failed to disclose information material to his or her decision to consent to a particular intervention. Only half of American jurisdictions accept the core principle enunciated in *Canterbury v. Spence* that the patient's need for information to effectuate self-determination requires a standard of disclosure established by law (the reasonable patient standard), rather than professional custom (what a reasonable physician concludes a

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forever at war with the mutual expectations of the parties.”).

<sup>32</sup> *Kelley v. Middle Tenn. Emerg. Physicians, P.C.*, 133 S.W.3d 587, 593 (Tenn. 2004); *Mead v. Legacy Health Sys.*, 352 Or. 267 (2012); *Green v. Walker*, 910 F.2d 291, 293 (5th Cir. 1990). *See also* M Shultz, *supra* note 12, at 223–24 (1985). This contractual relationship may either be express or implied. Similarly, it has been held that a consent form in a research protocol formed a unilateral contract. *See Dahl v. Hem Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993).

<sup>33</sup> *See, e.g., Betesh v. United States*, 400 F. Supp. 238 (D.D.C. 1974); *Kundert v. Il. Valley Comm. Hosp.*, 964 N.E. 2d 670 (Ill. App. Ct. 2012); *Reynolds v. Decatur Mem. Hosp.*, 277 Ill. App. 3d 80 (1996) (holding that there was no physician-patient relationship between a doctor who gave an informal opinion over the telephone at the request of the treating physician and a minor patient whose case was discussed, and thus the doctor did not owe duty of care to patient).

<sup>34</sup> *See generally Betesh v. United States*, 400 F. Supp. 238 (D.D.C. 1974).

<sup>35</sup> BERG ET AL., *supra* note 4, at 141.

patient ought to know).<sup>36</sup> In other words, half of the states use the “reasonable patient” standard of *Canterbury*,<sup>37</sup> while half use “professional” standard (like that employed in other medical malpractice cases).

Decisions addressing informed consent arising in the treatment context have also been premised on the physician’s fiduciary duty to her patient.<sup>38</sup> A fiduciary duty claim, or one that is based on an individual’s obligation to act for another’s benefit, requires that the patient show that (1) had he known of a certain risk, he would have behaved differently; and (2) another approach would have resulted in a different outcome. However, generally, “the standard physician-patient relationship is not always deemed fiduciary in the most classic sense.”<sup>39</sup>

#### B. Informed Consent to Research

Unsurprisingly, the focus on the doctrine of informed consent came to the forefront in the research context at the same time as it did in the treatment context. However, research participants who are harmed in the course of medical research rarely have a right to recover for lack of informed consent. The law as it relates to the failure of investigators to disclose risks in the research context developed statutorily, rather than judicially.<sup>40</sup> This fundamental distinction in the doctrine of informed consent between treatment and research is central to the absence of judicial recourse for research participants who are harmed as a result of investigators’ failure to disclose the risks of research.

The modern history of human subjects research can be traced back to the Nazi experiments during World War II and the Nuremberg War Crimes Trials against twenty-three doctors who had performed medical experiments without the subjects’—prisoners of war and

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<sup>36</sup> David M. Studdert et al., *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risk*, 4 J. EMPIRICAL LEGAL STUD. 103 (2007).

<sup>37</sup> *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

<sup>38</sup> *Shea v. Esenstein*, 107 F.3d 625 (8th Cir. 1997). However, in *Neade v. Portes*, 193 Ill. 2d 433 (2000), the Illinois Supreme Court rejected the use of fiduciary theories to protect patients from risks created by provider’s third party financial arrangements, like managed care organizations.

<sup>39</sup> Morreim, *supra* note 4, at 4 (citing J.C. SHEPHERD, THE LAW OF FIDUCIARIES 29 (1981) (discussing the historical shift away from holding doctor-patient relationship to be fiduciary because of the doctor’s superior education)).

<sup>40</sup> BERG ET AL., *supra* note 4, at 258 (“The very fact that consent to treatment has been left to judicial control, while consent to research is regulated by administrative bodies, points to a fundamental distinction between the treatment and research processes.”).

civilians of occupied countries—consent. The resulting 1947 Nuremberg Code, authored by the expert witnesses and judges in the “Doctors Trial,” is a set of research ethics principles for human experimentation and emphasizes the principles of autonomy and respect for persons.<sup>41</sup> However, since then, the U.S. has had its own major research scandals. In one of the most notorious studies, United States Public Health Service researchers investigating the progression of syphilis failed to treat participants or inform them of available treatments, even after penicillin became widely available for treatment.<sup>42</sup> From 1932 to 1972, nearly 400 impoverished African Americans were included in the study, many of whom died of syphilis or syphilis-related conditions. The experiment, which became known as the Tuskegee Syphilis Study, persists as an infamous example of non-consensual, harmful research.<sup>43</sup>

In light of the revelation of scandals such as the Tuskegee Syphilis study and those revealed by Henry Beecher’s groundbreaking 1966 article in the *New England Journal of Medicine*,<sup>44</sup> lawmakers at both the federal and state levels have attempted to create oversight mechanisms for human subjects research, with the goal of protecting the rights of participants from harmful, unethical research. These laws and regulations focus on voluntary informed consent and oversight to protect research participants from abuse. In 1974, Congress passed the National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral

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<sup>41</sup> See *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10* (1949) available at <http://www.hhs.gov/ohrp/archive/nurcode.html>.

<sup>42</sup> Tuskegee Syphilis Study Legacy Committee, *Final Report of the Tuskegee Syphilis Study Legacy Committee – May 20, 1996*, <http://exhibits.hsl.virginia.edu/badblood/report/> (last visited Nov. 9, 2014).

<sup>43</sup> *Id.*

<sup>44</sup> Henry K. Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 367, 371 (1966), <http://www.hhs.gov/ohrp/archive/documents/BeecherArticle.pdf>. In one example, the Willowbrook State School, a New York residential institution for developmentally disabled persons, asked parents to give “consent” for the deliberate infection of their children with hepatitis, although the risks to the children were not disclosed. Some of the children were then treated with immunoglobulins in an attempt to diminish the effect of the disease, while others served as control subjects. In some cases, children waiting for admission to the institution gained entry when parents agreed to enroll their child in the study since the only available rooms were in the experimental ward. In another instance cited in the article, researchers from Memorial Sloan-Kettering injected cancer cells into twenty-two institutionalized elderly patients at the Jewish Chronic Disease Hospital. Patients were not informed that they were exposed to cancer but were told only that they would receive “some cells.” *Id.* at 371.

Research (“National Commission”).<sup>45</sup> One of the responsibilities of the National Commission was to identify the ethical principles that should be the foundation of human subjects research and to develop guidelines to assure that such research is conducted in accordance with those principles.

The National Commission’s 1978 report, also known as the Belmont Report, enunciated three ethical values by which research involving human subjects should be conducted: respect for persons, beneficence, and justice.<sup>46</sup> The first of these values, respect for persons, addresses the primary ethical imperative that individuals should be respected as autonomous agents.<sup>47</sup> An autonomous individual can consider and act upon personal goals, and to respect an autonomous individual is to accept his opinions and decisions—so long as these actions do not harm others. The value of respect for persons encourages potential participants to be involved in the decision-making process, assuring them that they have an essential role in the research and that their opinions and decisions are valued. It also reminds investigators that all participants should be treated with dignity and respect, and that they are not merely objects to be used for the purpose of research.

In turn, the Belmont Report became the basis for much of the federal Department of Health and Human Services (HHS) regulations, including the Common Rule, which now govern the majority of human subjects research in the country.<sup>48</sup> With its focus on

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<sup>45</sup> THE NAT’L COMM’N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT (1979), *available at* <http://www.hhs.gov/ohrp/policy/belmont.html>.

<sup>46</sup> *Id.*

<sup>47</sup> The original Belmont Report detailed the value of autonomy thusly:  
An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to an autonomous person’s considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

*Id.*

<sup>48</sup> 45 C.F.R. 46 (Subpart A) (2014). The Common Rule (formally “The Federal Policy for the Protection of Human Subjects”) has been adopted by eighteen federal government agencies to promote uniformity in the conduct of human subjects research. Research is primarily overseen by the Office of Human Research Protections (OHRP), an office within HHS, which ensures regulatory compliance and provides guidance for the conduct of such research. *See generally* US Department of Health and Human Services, *OHRP Fact Sheet – December, 2009*, <http://www.hhs.gov/ohrp/about/facts/index.html> (last visited Nov. 15, 2014). Only Subpart A of 45 C.F.R. 46 (2014),

beneficence, justice, and—most important to this discussion—autonomy, the Common Rule applies to research that uses federal funds, is conducted by the federal government, or is overseen by a federal agency.<sup>49</sup> The Common Rule and similar FDA regulations<sup>50</sup> are intended to protect research participants by minimizing the possibility of coercion or undue influence by laying out the requirements for informed consent. Among its other elements, the Common Rule enunciates detailed requirements regarding institutions' responsibilities to assess research protocols and for obtaining and documenting informed consent, including disclosure of potential risks and benefits.<sup>51</sup>

However, neither the Common Rule nor the FDA regulations—the most significant federal regulations related to human subjects research—provide a private right of action for participants who are harmed as a result of investigators' failure to disclose the risks of the research. The lack of a private right of action for research harms can be attributed to the absence of a recognized relationship between the investigator and the participant. In the treatment context, the doctor-patient relationship gives rise to a duty of the physician to the patient; breach of that duty allows the injured patient to recover for damages in civil suit.<sup>52</sup> Because a similar relationship does not exist between the investigator and research participant, a researcher's duty of informed consent to study participants is limited. Instead, in the absence of a therapeutic relationship, the penalty for violation of the regulations governing human subjects research is loss of federal funding or suspension of research.<sup>53</sup>

Historically, the relationship between the investigator and research participant has been easily distinguishable from the relationship between the doctor and patient. For one, to the extent that the doctor-patient relationship is a fiduciary one, the investigator-

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the Basic HHS Policy for Protection of Human Research Subjects, is identified as the Common Rule. The Common Rule is also consistent with the Declaration of Helsinki (recommendations by the World Medical Association (WMA) for research involving human subjects). The Declaration of Helsinki was originally adopted by the WMA in 1964, and the most recent amendments were adopted in October 2013.

<sup>49</sup> 45 C.F.R. § 46.101 (2014).

<sup>50</sup> 21 C.F.R. § 50 (2014). The FDA regulations are substantially similar to the Common Rule.

<sup>51</sup> 45 C.F.R. §§ 46.116–17 (2014).

<sup>52</sup> See *supra* Section I.O.

<sup>53</sup> Office for Human Research Protections (OHRP), Department of Health and Human Services, *OHRP's Compliance Oversight Procedures for Evaluating Institutions* (Oct. 14, 2009), available at <http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf>; 45 C.F.R. § 46.123(a) (2014); 21 C.F.R. § 56.121 (2014).

research participant relationship is not.<sup>54</sup> In the treatment context, a physician has a direct obligation to provide care to the patient, with the purpose of preserving or improving her health. This purpose lends itself to an expectation of trust and confidence upon which a fiduciary relationship may be based. In contrast, the investigator's interaction with a study's participant is for the advancement of generalized knowledge—and *not* the direct (or even often indirect) benefit to the research participant.<sup>55</sup> Thus, “a completely different allegiance permeates the relationship. The investigator's entire purpose, his number one loyalty, is already pegged on something other than the patient. It is to the protocol.”<sup>56</sup>

Although lawsuits based on failure of informed consent against investigators have increased in the last few decades,<sup>57</sup> those courts that

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<sup>54</sup> Morreim, *Medical Research Litigation and Malpractice Tort Doctrines*, *supra* note 4, at 45; Elizabeth R. Pike, Karen Rothenberg & Benjamin E. Berkman, *Finding Fault?: Exploring Legal Duties to Return Incidental Findings in Genomic Research*, 102 GEO. L.J. 795, 818 (2014) (“But researchers *qua* researchers are not generally thought to owe fiduciary duties, despite often having similar knowledge, skills, and abilities . . . . Researchers, therefore, owe participants something less than a fiduciary duty.”).

<sup>55</sup> Coleman, *supra* note 3; BERG ET AL., *supra* note 4, at 281; Matthew Gordon, *A Legal Duty to Disclose Individual Research Findings To Research Subjects?*, 64 FOOD & DRUG L.J. 225 (2009). Gordon notes that the traditional approach is beginning to break down: “The traditional rule regarding third-party examinations is changing, however, and with it the implications for researchers' disclosure duties to their subjects. In a number of jurisdictions, courts have been unwilling to rigidly apply the formal requirements of a physician-patient relationship when faced with preventable harm.” *Id.* at 238. See also Morreim, *supra* note 4, at 45.

<sup>56</sup> Morreim, *supra* note 4, at 45. See also PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 6, at 91 (“Whereas clinicians have strong fiduciary duties to act in the best interests of patients, researchers have obligations to their participants and to society. Both society at large and participants engaged in research have a vested interest in completed research that furthers scientific knowledge.”); Pike, *supra* note 4, at 12 ([T]rust and dependency are “not the cornerstone of the researcher-participant relationship.”).

<sup>57</sup> See, e.g., Mello, Studdert & Brennan, *supra* note 4, at 40; Morreim, *supra* note 4, at 4; Alice Dembner, *Lawsuits Target Medical Research—Patient Safeguards, Oversight Key Issues*, BOSTON GLOBE, Aug. 12, 2002, at A1. The case of Jesse Gelsinger exemplifies what some commentators have noted to be a proliferation of (often unsuccessful) tort litigation against researchers. An eighteen-year old volunteer with ornithine transcarbamylase deficiency died during his participation in a gene transfer study at the University of Pennsylvania. The lawsuit brought by his father against the university and investigators alleged that the investigators committed fraud by not revealing that a co-investigator, the university, and other university officials had financial relationships with Genovo, a biotechnology company, and stood to gain financially from the successful use of RDAd vectors. Complaint, *Gelsinger v. Trustees of the Univ. of Pa.* (2000), [http://www.sskrplaw.com/files/gelsinger\\_complaint.pdf](http://www.sskrplaw.com/files/gelsinger_complaint.pdf). The complaint also alleged that the investigators had failed to inform Jesse of the risks of the study, that they had failed to inform Jesse or the FDA of adverse events experienced by other participants in the same trial as well as the death of monkeys in an earlier

have attempted to establish a private cause of action for failure to provide informed consent in research have rarely—if ever—been successful.<sup>58</sup> Because of the absence of a duty of care premised on a recognized relationship between investigators and research participants in the current rules governing human subjects research, courts are generally reluctant to recognize a duty-conferring relationship between the investigator and research participant.<sup>59</sup> In most instances where courts have found a duty-conferring relationship in the research context, they have done so based on a preexisting doctor-patient interaction, such that the physician serves a dual role (as does the patient). For example, in *Darke v. Isner*, the Massachusetts Superior Court held that the state common law was broad enough to impose tort liability on a doctor who failed to disclose his financial interest in the treatment he recommended.<sup>60</sup> Roger Darke, a participant in an experimental gene therapy program conducted by Dr. Jeffrey Isner, chief of cardiovascular research at St. Elizabeth's Medical Center in Boston, died twenty-four hours after undergoing surgery in which Isner administered a gene therapy.<sup>61</sup> Darke's widow sued the hospital and doctors, alleging that, had Darke known that a previous patient had died in the program and that Isner had financial interests in the success of the gene therapy program, Darke would not

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animal study, and that the investigators had allowed Jesse to participate in the study despite not meeting its inclusion criteria due to the fact that his liver was not functioning within the study's 24-hour limit. Jesse Gelsinger's father learned that a "principal investigator, James Wilson, owned stock in . . . [the] company [he had] founded, which contributed \$4 million per year to human gene therapy research at the University . . . where the experiment took place," and claimed that had Gelsinger known about these financial interests, "he would not have [participated] in the research study." David Resnik, *Disclosing Conflicts of Interest to Research Subjects: An Ethical and Legal Analysis*, 11 ACCOUNTABILITY IN RESEARCH 141, 142 (2004). The suit ended in a confidential settlement in 2000.

<sup>58</sup> Federal courts have generally rejected a private right of action. See *Robertson v. McGee*, 2002 WL 535045, at \*3 (N.D. Okla. 2002); *Robinett v. U.S.*, 62 F.3d 1433, at 1 (Fed. Cir. 1995); *Washington v. Catalona*, 437 F. Supp. 2d 985, 1000 (E.D. M.O. 2006). A Pennsylvania court has found that a *hospital* could be held liable for failure to obtain informed consent in experimental studies pursuant to FDA regulations. *Friter v. Iolab Corp.*, 414 Pa. Super. 622 (1992). The court, however, appears to conflate the patient's and the research participant's rights to informed consent, noting that the plaintiff had been a patient of the hospital and "was never informed, prior to surgery, that he was about to become a participant in a clinical investigation." *Id.* at 624. The court held that the unconsented-to operation was a non-consensual touching, "thus giving rise to an action for a 'technical' battery." *Id.* at 627.

<sup>59</sup> Wolf, Paradise & Caga-anan, *supra* note 30, at 368 (citing *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (W.D. Wa. 2002)).

<sup>60</sup> *Darke v. Isner*, 20 Mass. L. Rep. 419 (Mass Super. Ct. 2005).

<sup>61</sup> *Id.*



have participated.<sup>62</sup> At the time the suit was filed, Isner and his heirs owned 20 percent of Vascular Genetics, which Isner helped found in 1997 to support the experimental gene therapy treatment for coronary artery disease that he developed (the defendant hospital also owned 20 percent). The complaint alleged that Darke “was intentionally and maliciously treated as a human guinea pig in order to generate great financial profits for all defendants.”<sup>63</sup>

The trial court held that the doctor and hospital could be held liable for failing to disclose, as part of the informed consent process, their financial interests in the treatment that they recommended.<sup>64</sup> The court repeatedly refers to Isner as Darke’s “doctor” and relies on the reasoning that supports the duty of care (and the associated duty to disclose financial conflicts of interest) based on a *medical* physician-patient relationship.<sup>65</sup> Again, the next year, the same court held that enough evidence had been presented to support the allegation that the doctor’s financial stake in the success of the gene therapy treatment may have compromised how the clinical trial was conducted, and that enough evidence was presented to demonstrate the existence of a *doctor-patient* relationship between Darke and Isner.<sup>66</sup> It also held that the hospital and doctor failed to disclose the financial relationships to Darke and his wife. Despite all of this, the jury ultimately found for the defendants.

Courts have also generally refused to find that the federal rules and regulations governing informed consent in research give rise to a private right of action for research participants. For example, in *Wright v. Fred Hutchinson Cancer Research Center*, family members of cancer patients who had participated in a clinical trial sued the Fred Hutchinson Cancer Research Center (the Hutch) and its investigators in an attempt to enforce the Common Rule, Nuremberg Code, and Declaration of Helsinki.<sup>67</sup> The clinical trial tested use of a monoclonal antibody to reduce the risk of graft-versus-host disease in bone marrow transplant recipients. The antibody caused graft rejections, cancer

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<sup>62</sup> Complaint, *Darke v. Isner*, No. 02-2194-E (Mass. Super. Ct. Aug. 2, 2002).

<sup>63</sup> *Id.*

<sup>64</sup> *Darke v. Isner*, 17 Mass.L. Rep. 689 (Mass Super. Ct. 2004).

<sup>65</sup> The court only once refers to “research,” in relying on “various guidelines promulgated by professional medical organizations as well as by the federal government” to support a requirement of consent forms in research. However, the court continues to inappropriately conflate treatment and research, explaining that these guidelines and the Common Rule “indicate a trend towards requiring physicians to disclose non-medical information to the patient.” *Id.*

<sup>66</sup> *Darke v. Isner*, 20 Mass. L. Rep. 419 (Mass Super. Ct. 2005).

<sup>67</sup> 269 F. Supp. 2d 1286 (W.D. Wash. 2002).

relapses, and new cancers, which the plaintiffs alleged caused premature death in some trial participants. The *Seattle Times* exposed that the Hutch had licensed the commercial rights to the antibody being studied to a start-up company called Genetic Systems but retained a royalty interest and held stock in the company.<sup>68</sup> In addition, one of the investigators had a seat on the Genetic Systems' scientific advisory board, another was employed as the company's medical director in addition to working for the Hutch, and the third was a consultant to the company. The plaintiffs claimed that the defendants failed to disclose the risks of trial participation and the financial interests of the Hutch and investigators involved in the study violated the rights of trial participants. The trial court disagreed, holding that withholding information did not violate the trial participants' rights.<sup>69</sup> It also rejected a claim brought under the Civil Rights Act to enforce the federal regulations, holding that the Food, Drug, and Cosmetic Act (FDCA) does not create or imply a private right of action.<sup>70</sup> The court reasoned that regulations promulgated by an agency cannot give rise to a private cause of action if the authorizing statute does not confer that right.

Further, even where courts have found a relationship between the investigator and research participant, they have often been unable to find adequate materiality or causation to support a private right of action for informed consent in research.<sup>71</sup> In the research context, it is particularly difficult to show that individuals would not have participated in a research protocol had they known of certain risks. Often, participation in a study is an individual's final option, after she has exhausted all of the treatment alternatives. In *Wright v. Fred Hutchinson Cancer Research Center*, the court did allow the informed consent claim to proceed to trial.<sup>72</sup> However, the jury found for the Hutch and investigators, concluding that the participants had given

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<sup>68</sup> Duff Wilson & David Heath, *Patients Never Knew They the Full Danger of Trials They Staked Their Lives on*, SEATTLE TIMES (2001), available at [http://seattletimes.com/uninformed\\_consent/bloodcancer/story1.html](http://seattletimes.com/uninformed_consent/bloodcancer/story1.html).

<sup>69</sup> *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (W.D. Wash. 2002).

<sup>70</sup> *Id.* (relying on *Robertson v. McGee*, No. 01CV60, 2002 WL 535045, at \*3 (N.D. Okla. Jan. 28, 2002); *Robinett v. United States*, 62 F.3d 1433 (Fed. Cir. 1995)).

<sup>71</sup> Lori A. Alvino, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 910 (2003) ("In all cases the injured plaintiff would have to prove the basic elements of a negligence cause of action . . . . Depending on the situation, injured research subjects could have a great deal of difficulty proving any one of these elements.").

<sup>72</sup> *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (W.D. Wash. 2002).

their consent and that a reasonably prudent fully informed person in their position would have made the choice to participate in the clinical trial.<sup>73</sup>

In contrast to *Wright*, *Whitlock v. Duke University* represents one of the few cases where a court has held that the Common Rule established the standard of care for an informed consent claim against investigators where there was no preexisting medical relationship between the researcher and participant.<sup>74</sup> The court attempted to distinguish research from treatment and imposed a researcher standard of care on the investigator.<sup>75</sup> The participant, Leonard Whitlock, participated in a simulated deep dive experiment to study high pressure nervous syndrome, as a result of which he suffered permanent organic brain damage. Among other claims, Whitlock alleged that Duke University negligently failed to warn Whitlock of the risk of organic brain damage. Although the court explained that “the degree of required disclosure of risks is higher in the nontherapeutic context” than in the nonexperimental therapeutic context controlled by the state statute at issue, it held that there was no genuine issue of fact regarding whether the risk of organic brain damage unique to experimental deep diving was a reasonably foreseeable risk.<sup>76</sup> It therefore granted summary judgment to Duke University on the negligence issue and did not reach the issue of whether a private cause of action in favor of a research subject arises from the Common Rule.<sup>77</sup>

Where courts have found that participants can bring a claim for lack of informed consent in the research context, they have primarily done so in cases involving particular populations or where (like in *Whitlock*) the investigator has neglected to disclose information about his research or economic interests that may affect his professional

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<sup>73</sup> *Id.*

<sup>74</sup> 637 F. Supp. 1463, 1475 (M.D.N.C. 1986). *See also* *Vodopest v. MacGregor*, 913 P.2d 779 (Wash. 1996) (adopting the Common Rule as the standard of care for informed consent claims).

<sup>75</sup> *Whitlock*, 637 F. Supp. 1475.

<sup>76</sup> *Id.* at 1471. *See also* Anna C. Mastroianni, *Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy*, 16 HEALTH MATRIX 351, 420 (2006) (“[A] higher standard of disclosure would appear to apply to research than to medical practice.”).

<sup>77</sup> *Whitlock*, 637 F. Supp. at 1475. The Fourth Circuit Court of Appeals affirmed. *Whitlock v. Duke Univ.*, 829 F.2d 1340 (4th Cir. 1987). One commentator argues that the court failed to distinguish clinical innovation (a genre of medical practice) from research, the latter requires “a scientific protocol toward gaining generalizable knowledge.” Morreim, *supra* note 4, at 27 (stating that “although the court ostensibly distinguishes between medical treatment and research, its decision was based on an important confusion” between research and medical innovation in the precedent upon which the court relied).

judgment.<sup>78</sup> Despite courts' inability or unwillingness to recognize a private right of action for informed consent in the *research* context, the *Grimes v. Kennedy Krieger Institute* decision is frequently cited as evidence that courts are beginning to recognize the existence of a duty and standard of care arising out of the "special relationship" between investigators and research participants established by the Common Rule. The Kennedy Krieger Institute, a research institute associated with Johns Hopkins, conducted a non-therapeutic research program testing the effectiveness of varying degrees of lead paint abatement in housing inhabited by young children.<sup>79</sup> With funding from the Environmental Protection Agency, it studied the blood lead levels found in children who lived in remediated, partially remediated, and "modern" housing in the Baltimore area. Thus, the study "required certain classes of homes to have only partial lead paint abatement modifications performed . . . [and] encouraged, and in at least one of the cases . . . required, the landlords to rent the premises to families with young children."<sup>80</sup>

The trial court found for the investigators, and the Maryland Court of Appeals reversed.<sup>81</sup> The Court of Appeals held that the Common Rule's informed consent requirements create a duty of care arising out of a "special relationship" between the investigator and research participant, a breach of which was actionable under state law. The court held that the research consent form specifically created a contract and that the consent form was inadequate.<sup>82</sup> Thus, the protocol lacked fully informed consent as required by the federal regulations. The court stated that the standard for disclosure is whether a reasonably prudent fully informed person would have decided to participate in the research. The participant (or his surrogate) is entitled to disclosure of all "reasonably foreseeable" risks of the research. The court predicated its decision on the establishment of a so-called "special relationship" between the investigator and the research participant, which can give rise to duties for both the investigator and the research participant or surrogate, even where the investigator is not the research subject's physician (and therefore no doctor-patient relationship exists). Instead, the duty of care arises out of the investigator-subject relationship, and because the investigators

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<sup>78</sup> See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

<sup>79</sup> *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

<sup>80</sup> *Id.* at 811–12.

<sup>81</sup> *Id.*

<sup>82</sup> "The very nature of nontherapeutic research on human subjects can, and normally will, create special relationships out of which duties arise." *Id.* at 834–35.

waited nine months to disclose “hot spots” of high lead exposure to parents (after the child’s blood was found to contain elevated levels of lead), they breached the duty to disclose complete and accurate information.

The *Grimes* court makes a particularly concerted effort to find the existence of a “special relationship” that gives rise to duties. However, the decision indicates that such a finding may be constrained to particularly circumscribed conditions.<sup>83</sup> For example, the court was willing to find the existence of an investigator-participant relationship because the facts in that case involved (1) surrogate consent to research, which offered (2) no prospect of direct benefit to the research participants (in other words, the research protocol was nontherapeutic), but presented (3) more than a minor increase over minimal risk to the (4) otherwise healthy participants.<sup>84</sup> Thus, a court may be more likely to determine that a “special relationship” exists where investigators recruit otherwise healthy individuals, “especially children whose consent is furnished indirectly, to participate in nontherapeutic procedures that are potentially hazardous, dangerous, or deleterious to their health.”<sup>85</sup> Significantly, no other court has found such a “special relationship” between investigators and research participants, and it would be presumptuous to assume, based on this single court’s narrow holding, a general private right of action for participants for failure to disclose the risks and benefits of a research protocol.<sup>86</sup>

## II. THE EVOLVING RESEARCH MODEL AND THE SHIFTING INVESTIGATOR-PARTICIPANT RELATIONSHIP

The practice of medicine has changed dramatically in the last four decades, arguably blurring the line between research and treatment.<sup>87</sup> The doctor-patient relationship is itself transforming, becoming less permanent and more impersonal—much like the traditional investigator-participant relationship. For example, patients often rely on multiple specialists (for finite amounts of time each) rather than a single generalist over the course of their lifetime, thereby contributing to less lasting relationships. This may signal a “knowledge transition” in the conventional practice of medicine, where “the growth of

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<sup>83</sup> The court makes clear that whether such a relationship exists should be determined on a “case by case” basis. *Id.* at 858.

<sup>84</sup> *Id.* at 846.

<sup>85</sup> *Grimes*, 782 A.2d 807, 845–46.

<sup>86</sup> See Hoffmann & Rothenberg, *supra* note 30; Alvino, *supra* note 71, at 910.

<sup>87</sup> Gold, *supra* note 19, at 135.

medical knowledge caused a shift from a treatment that is provided by one (familiar) physician to a treatment provided by several (unknown) specialists and sub-specialists.”<sup>88</sup> Further, the provision of care increasingly involves more advanced technology, signaling a “technological transition,” in which “advanced technological equipment became an integral and prominent component of medical evaluation and treatment.”<sup>89</sup> The “structural transition” in the conventional practice of medicine is exacerbated by the increasing role of insurance companies or hospitals.<sup>90</sup> Moreover, the information disparity traditionally present in the doctor-patient relationship continues to dissipate. Thus, the doctor-patient relationship is becoming more like that of the investigator-patient: more transitory, impersonal, and indirect.

Maintaining the distinction between the duties owed to patients and duties owed to research participants may become even less sustainable as the distinctions between treatment and research continue to diminish. Research participants are often subject to the same procedures and risks as patients (but frequently are not presented with the attendant potential benefits of an intervention). Further, calls for similar approaches to both of these relationships—including compensation for injured patients and participants—often hinge on the comparable information disequilibrium that exist in each. The *Grimes* court noted disparate knowledge levels between investigators and subjects in the research context, explaining that the “special relationship” between investigators and research participants “arise because, generally, the investigators are in a better position to anticipate, discover, and understand the potential risks to the health of their subjects. Practical inequalities exist between researchers, who have superior knowledge, and participants ‘who are often poorly placed to protect themselves from risk.’”<sup>91</sup>

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<sup>88</sup> Gold, *supra* note 19, at 135.

<sup>89</sup> Gold, *supra* note 19, at 135.

<sup>90</sup> Gold, *supra* note 19, at 135. The author notes a fourth transition in the practice of medicine that is less relevant to this analysis, the epidemiological transition, where “the overall prevalence and lethality of infectious diseases has been reduced significantly while there has been a relative rise in the overall prevalence of chronic and degenerative conditions.” Gold, *supra* note 19, at 135.

<sup>91</sup> *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 851 (Md. 2001) (citation omitted).

The fact that consent to the treatment is left to judicial control, while consent to the research is left to statutory and regulatory control, may reflect the traditional distinction between treatment and research.<sup>92</sup> However, at the same time as the physician-patient relationship has become less permanent and personal, the typical research model has evolved since the most notable court efforts to find a duty of care, premised on a special relationship<sup>93</sup>—thereby making the line between treatment and research less well-defined. In turn, courts may be less able to rely on the distinction between treatment and research goals as a justification for different standards for recovery for nondisclosure of material information. In fact, there is evidence that courts have begun to recognize the artificiality of the distinction between treatment and research.<sup>94</sup> For example, in 1976—two years after the passage of the National Research Act—a federal appeals court applying New Mexico law addressed the increasingly unclear line between treatment and experimental procedures.<sup>95</sup> In *Ahern v. Veterans Administration*, a patient brought a medical malpractice action against the Veterans Administration (VA) for negligently administering excessive amounts of radiation in the treatment of a cancerous tumor.<sup>96</sup> The chief of surgical services at the VA testified that no medical research supported deviating from the standard of care.<sup>97</sup> The plaintiff's physician similarly testified that, in his opinion, administering the dosage of radiation was "experimental."<sup>98</sup> Focusing on the "experimental nature" of the intervention, the court held that, "in order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be *fully informed* of the

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<sup>92</sup> BERG ET AL., *supra* note 4, at 259.

<sup>93</sup> *Grimes*, 782 A.2d 807.

<sup>94</sup> However, not all scholars agree that research and treatment are similar enough to warrant this possible conflation. See Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomic Research*, 14 GENETICS IN MED. 473 (2012). Others maintain that the obligations of researchers must be different from those of treating physicians. Coleman, *supra* note 3, at 403 (recommending reliance on fiduciary law as a model for the researcher-subject relationship); Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking About the Clinical Care that Researchers Owe Their Subjects*, 34 HASTINGS CTR. REP. 25, 25 (2004) ("Researchers do not owe their subjects the same level of care that physicians owe patients, but they owe more than merely what the research protocol stipulates. In keeping with the dynamics of the relationship between researcher and subject, they have limited but substantive fiduciary obligations.").

<sup>95</sup> *Ahern v. Veterans Admin.*, 537 F.2d 1098 (10th Cir. 1976).

<sup>96</sup> *Id.* at 1099.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 1101.

*experimental nature* of the treatment and of the foreseeable consequences of that treatment.”<sup>99</sup>

Moreover, the oft-cited case *Moore v. Regents of the University of California* highlights the increasingly blurred line between the treatment and research relationships.<sup>100</sup> The Supreme Court of California held that a patient with hairy cell leukemia had a cause of action based on his physician’s failure to disclose his intent to use portions of the plaintiff’s spleen in research for which the physician hoped to benefit financially.<sup>101</sup> The court then remanded the case for trial on the grounds that the patient, Moore, had alleged a valid cause of action because Golde, Moore’s physician, did not disclose facts “material to the patient’s consent.”<sup>102</sup> Failure to disclose such interests may “give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.”<sup>103</sup> Moore’s physicians represented that the taking of Moore’s cells was solely or primarily for research rather than for therapeutic purposes. Moore alleged that his physician concealed his nontherapeutic interests, telling Moore that the takings were required for Moore’s health and well-being and denying any commercial or financial interest in the cells.<sup>104</sup> The court decided that the physician had an obligation to disclose the research and economic purposes of the tissue he extracted during the splenectomy, which would be material to the patient’s decision to undergo treatment.<sup>105</sup> The court therefore held that a

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<sup>99</sup> *Id.* at 1102 (emphasis added).

<sup>100</sup> *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493 (Cal. 1990). *But see* *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003) (noting that “since the law regarding a duty of informed consent for research subjects is unsettled and fact-specific . . . , the Court finds that in certain circumstances a medical researcher does have a duty of informed consent[.]” but declining to extend the duty to disclose economic interests where a researcher is not in a therapeutic relationship with the patient). The court in *Greenberg* found that *Moore* was “clearly distinguishable” because of this lack of clinical dependence between the parties. *Id.* Further, although the court in *Greenberg* noted in dicta that a duty may attach at some point in the investigator-participant relationship, the duty of informed consent in medical research has not been extended to disclosure of a researcher’s economic interests. *Id.*

<sup>101</sup> *Moore*, 793 P.2d at 493.

<sup>102</sup> *Id.* at 484.

<sup>103</sup> *Id.* at 483.

<sup>104</sup> *Id.* at 481.

<sup>105</sup> *Id.* at 484. Some commentators have described the problematic nature of conflating research and treatment in this case, noting that “the medically pointless tissue removals could not have been malpractice because they were not medical practice at all . . . [because] medical treatment aims ‘to benefit or cure the patient.’” Morreim, *supra* note 4, at 22 (quoting *Craft v. Vanderbilt Univ.*, 18 F. Supp. 2d 786, 796 (M.D. Tenn. 1998)).



physician who used a patient's surgically removed spleen to establish a patented cell line should have disclosed his research and economic interests to the patient prior to the intervention.<sup>106</sup> This case highlights the lack of clarity regarding where treatment ends and research begins and is often relied upon to support the argument that the physician-patient relationship and investigator-participant relationship should be treated similarly.

Indeed, allowing harmed research participants the opportunity to recover might be even more necessary in the research context than in the treatment setting because of the greater probability of conflicting or diverging goals between investigator and research participant.<sup>107</sup> In fact, in addition to the knowledge gap between investigators and participants, this "misalignment of interests" was one of the theories upon which the *Grimes* court based its decision.<sup>108</sup>

### III. AN OBLIGATION TO DISCLOSE RESEARCH FINDINGS MAY FURTHER TRANSFORM THE INVESTIGATOR-PARTICIPANT RELATIONSHIP

As technology advances, the discovery of "research findings"<sup>109</sup>—incidental or secondary findings (results that arise that are outside the purpose of the research protocol<sup>110</sup>)—or other information that could affect the research participant's health or decision-making will become more likely and frequent. The proliferation of research protocols involving genetic and biological samples<sup>111</sup> or medical imaging will result in a wide range of potential research findings.<sup>112</sup> For example, the use of whole genome or exome sequencing "by nature produces incidental genomic findings, i.e., findings that have potential health or reproductive importance discovered in the course of conducting research but beyond the aims of the study."<sup>113</sup> In turn, an expectation that such research results should be returned to research participants may transform the investigator-participant relationship, giving rise to

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<sup>106</sup> *Id.*

<sup>107</sup> *Id.* at 16–17; BERG ET AL., *supra* note 4, at 281; *see also* Pike, *supra* note 4.

<sup>108</sup> Stephanie A. Alessi, *The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?*, 64 HASTINGS L.J. 1697, 1715 (2013).

<sup>109</sup> Eckstein, Garrett & Berkman, *supra* note 8, at 190.

<sup>110</sup> Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J. L. MED. & ETHICS 219 (2008).

<sup>111</sup> Rafael Dal-Ré et al., *Managing Incidental Genomic Findings in Clinical Trials: Fulfillment of the Principle of Justice*, 11 PLOS MED. 1, 1 (2014) ("Increasingly, clinical trials to develop new drugs and biologics involve whole genome or exome sequencing (WGS/ WES), including for biomarker characterization, for identification of genomic risk factors, and for population-based research.").

<sup>112</sup> Pike, Rothenberg & Berkman, *supra* note 54.

<sup>113</sup> Rafael Dal-Ré et al., *supra* note 111, at 1.

an obligation to disclose research findings. Eventually, this may open the door for a private right of action for failure to disclose the risks of a study.<sup>114</sup> Thus, the emerging duty of investigators to participants—a duty that may not have been as explicitly recognized in the past—may signify a new approach to how the law should approach the investigator-participant relationship. This section will explore the emerging ethical (and perhaps, legal) obligation to disclose research findings and how it will impact the investigator-participant relationship.

Whether there is an ethical duty to disclose the results of research to individual participants—whether or not the results are directly related to the central research inquiry—has become a central question in human subjects research.<sup>115</sup> In fact, in the last decade and a half, disclosure of research findings has been increasingly called for among scholars and research participants.<sup>116</sup> This is particularly true in genetics research.<sup>117</sup> For example, a 2009 survey found that 90 percent of 343 genetic researchers agreed that they had a duty to offer subjects aggregate research results.<sup>118</sup> And a 2013 study concluded that a

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<sup>114</sup> The reasoning in this Article is not predicated on the conclusion that there currently is a *legal* duty to return research findings to study participants; I believe that an ethical duty to disclose such findings is sufficient to demonstrate an evolving relationship between the investigator and the research participant. However, some scholars have begun to evaluate whether a researcher has a legal duty to return incidental findings. Pike, Rothenberg, & Berkman *supra* note 54, at 798 find:

Although there is no law or case law directly on point . . . there is a small possibility that a failure to appropriately return [incidental findings] could result in legal liability under law as it stands today. Furthermore, there is a greater likelihood of legal liability as scholars and researchers continue to advocate for an ethical obligation, particularly if returning [incidental findings] becomes widespread practice.

<sup>115</sup> Rosario Isasi et al., *Disclosure and Management of Research Findings in Stem Cell Research and Banking: Policy Statement*, 7 REGEN. MED. 439 (2012); Dal-Ré et al., *supra* note 111.

<sup>116</sup> Ann H. Partridge & Eric P. Winer, *Informing Clinical Trial Participants About Study Results*, 288 JAMA 363 (2002); Conrad Fernandez, Eric Kodish, & Charles Weijer, *Informing Study Participants of Research Results: An Ethical Imperative*, 25 IRB: ETHICS & HUMAN RESEARCH 12 (2003); David I. Shalowitz & Franklin G. Miller, *Disclosing Individual Results of Clinical Research*, 294(6) JAMA 737 (2005). However, some scholars have expressed concern about the increasing expectation that such information be returned to research participants. See Clayton & McGuire, *supra* note 94, at 473.

<sup>117</sup> See Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENET. MED. 565 (2013).

<sup>118</sup> Fiona Alice Miller et al., *What Does “Respect for Persons” Require? Attitudes and Reported Practices of Genetics Researchers in Informing Research Participants about Research*, 38 J. MED. ETHICS 48, 48 (2012). Despite the apparent widespread acknowledgment of a duty to return aggregate results, “return of aggregate results is still an uncommon practice in the United States.” Lynn G. Dressler, *Disclosure of Research Results from Cancer Genomic Studies: State of the Science*, 15 CLINICAL CANCER RES. 4270 (2009). See also

majority of researchers believe that research participants should have the option to receive at least some incidental genetic research results.<sup>119</sup> The ethical implications of requiring disclosure of research findings may be intensified as the discovery of clinically relevant and scientifically valid information becomes more frequent and donors increasingly express a desire to receive these findings.<sup>120</sup>

The transformation in the duty to disclose incidental or secondary findings is manifest in the evolution of national bioethics advisory body recommendations on the subject. In 1999, the National Bioethics Advisory Commission (NBAC) under President Clinton stated that disclosure of individual research participants' results "represents an exceptional circumstance" and recommended return of research findings only under narrowly specified conditions.<sup>121</sup> As evidence of changing perspectives, in December 2013, the Presidential Commission for the Study of Bioethical Issues released its report, which enunciated a series of recommendations for the management of incidental and secondary findings in both treatment and research.<sup>122</sup> The Presidential Commission explicitly acknowledged the fact that, in certain circumstances, researchers may have an ethical duty to disclose and manage incidental and secondary findings.<sup>123</sup>

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Rebecca Dresser, *Public Preferences and the Challenge to Genetic Research Policy*, 1 J. L. BIOSCIENCES 1 (2014).

<sup>119</sup> See Robert Klitzman et al., *Researchers' Views on Return of Incidental Genomic Research Results: Qualitative and Quantitative Findings*, 15 GENETICS IN MED. 888, 888 (2013).

<sup>120</sup> Juli Murphy et al., *Public Expectations for Return of Results from Large-Cohort Genetic Research*, 8 AM. J. BIOETHICS 36 (2008); Juli Murphy Bollinger et al., *Public Preferences Regarding the Return of Individual Genetic Research Results: Findings from a Qualitative Focus Group Study*, 14 GENETICS IN MED. 451 (2012); Nicole L. Allen et al., *Biobank Participants' Preferences for Disclosure of Genetic Research Results: Perspectives from the OurGenes, OurHealth, OurCommunity Project*, 89 MAYO CLINIC PROCEEDINGS 738 (2014).

<sup>121</sup> National Bioethics Advisory Commission (NBAC), *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (1999), at vi-vii, available at <http://bioethics.georgetown.edu/nbac/hbm.pdf>.

<sup>122</sup> PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 6.

<sup>123</sup> *Id.* at 79. See also Clayton & McGuire, *supra* note 94, at 473 ("There is substantial consensus that people should be offered results that could trigger interventions that are lifesaving or that could avert serious adverse health outcomes; there is somewhat less consensus about whether people should be offered results that may have reproductive implications or that could be personally meaningful."); Catherine Gliwa & Benjamin E. Berkman, *Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?* 13 AM. J. BIOETHICS 32, 33 (2013) ("[O]pinion seems to be moving toward the idea that there is some obligation to offer to disclose a limited set of findings."); Eckstein, Garrett & Berkman, *supra* note 8, at 190 ("There appears to be an emerging (but disputed) view that researchers have some obligation to disclose some genetic findings to some research participants."); Pike, Rothenberg & Berkman, *supra* note 54, at 9 ("By and large, scholars, practitioners, and advisory bodies agree

The nature and duration of the relationship between the research participant and the investigator may be the most important consideration in determining whether investigators owe research participants a duty to disclose research findings.<sup>124</sup> Noting that “researcher-participant relationships . . . vary in depth and duration,” the Presidential Commission called for “clear, consistent, and practical guidance” for researchers and institutions “about the ethical duties owed to research participants with respect to incidental and secondary findings.”<sup>125</sup>

Notably, arguments for disclosure of research findings are premised on the same principle upon which the requirements for informed consent rely.<sup>126</sup> In particular, the obligation is premised on the principle of autonomy: in order to make future autonomous and informed health care decisions, the participant has a right to know information discovered about him during the course of research. The return of genetic results demonstrates respect for individual autonomy and is being increasingly recognized as a “moral imperative.”<sup>127</sup> Thus, investigators may have an “affirmative duty . . . to truly give individuals the informational access that they deserve.”<sup>128</sup>

The ethical duty to return research findings has been described as potentially giving rise to “a legal obligation to offer findings of likely clinical or reproductive significance to research participants.”<sup>129</sup> Although there is no federal statutory requirement for disclosure of research results,<sup>130</sup> “[s]ome recent case law suggests that a legal trend may be emerging toward recognizing an obligation on the part of a researcher to provide a research participant with information acquired from a study, when that information has clinical implications for the participant.”<sup>131</sup> Commentators have noted the increasing potential for

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that researchers have an ethical obligation to offer to return some [incidental findings.]”). See also Wolf, Paradise & Caga-anan, *supra* note 30.

<sup>124</sup> Gaile Renegar et al., *Returning Genetic Research Results to Individuals: Points-to-Consider*, 20 *BIOETHICS* 24 (2006).

<sup>125</sup> PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 6, at 77.

<sup>126</sup> See *id.* This point will be discussed further in Part IV.A.

<sup>127</sup> See Misha Angrist, *You Never Call, You Never Write: Why the Return of “Omic” Results to Research Participants is Both a Good Idea and a Moral Imperative*, 8 *PER. MED.* 651 (2011).

<sup>128</sup> Alessi, *supra* note 108, at 1710.

<sup>129</sup> Wolf, Paradise & Caga-anan, *supra* note 30, at 367; see also Shalowitz & Miller, *supra* note 116; Vardit Ravitsky & Benjamin S. Wilfond, *Disclosing Individual Genetic Results to Research Participants*, 6 *AM. J. BIOETHICS* 8, 9 (2006).

<sup>130</sup> Federal regulations that govern the conduct of human subjects research, such as the Common Rule and FDA rules, provide no guidance on disclosing research results.

<sup>131</sup> Wolf, Paradise & Caga-anan, *supra* note 30, at 366; Pike, Rothenberg &

litigation claiming researcher negligence for failure to disclose to a subject an individual research finding of medical significance.<sup>132</sup> The *Grimes* decision has been cited as evidence that courts may impose a duty on investigators to inform study participants of research results.<sup>133</sup> However, in *Ande v. Rock*, the Wisconsin Court of Appeals dismissed an ordinary negligence claim that alleged that researchers failed to disclose an individual research finding indicating that the plaintiffs' child had cystic fibrosis.<sup>134</sup> The study focused on whether early nutritional intervention would improve outcomes for children afflicted with the disease. Despite the fact that the child was tested for the disease at birth as part of the study protocol, the plaintiffs were not informed that their daughter had cystic fibrosis. She was diagnosed with the disease at almost two years of age, at which point her mother was pregnant with the plaintiffs' second child, who was also afflicted with the disease.<sup>135</sup> In upholding the trial court's dismissal of the parents' negligence claims, the court decided that the parents failed to allege any duty-conferring relationship between themselves and the researchers.<sup>136</sup>

Informed consent law generally requires disclosure of research risks that are material and reasonably foreseeable.<sup>137</sup> Because secondary or incidental findings are discovered in the course of research, research participants cannot claim that the information would have been material to their initial decision to participate in the research protocol. However, many scholars and policy makers have called for disclosure of the possibility of discovering incidental or secondary findings in the course of a research protocol at the outset of research—i.e., during the informed consent process.<sup>138</sup>

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Berkman, *supra* note 54. Wolf, Paradise, and Caga-anan discuss *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803 (N.D. Ill. 1999), in which an investigator had a duty, absent a physician-patient relationship, to warn the research participant of the findings that he might be at "greater risk of neural tumors in a way that might have permitted their earlier detection and removal or other treatment." *Supra* note 30, at 370. According to the authors, the case "suggest[s] that researchers indeed have legally cognizable duties towards research participants, although the scope of these duties is not yet well-defined." *Supra* note 30, at 370.

<sup>132</sup> Gordon, *supra* note 55, at 226.

<sup>133</sup> Gordon, *supra* note 55, at 234.

<sup>134</sup> 647 N.W. 2d 265, 269 (WI Ct. App. 2002).

<sup>135</sup> *Id.* at 270.

<sup>136</sup> *Id.* at 276.

<sup>137</sup> See *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

<sup>138</sup> The Presidential Commission recommended that "[d]uring the informed consent process, researchers should describe the types of incidental and secondary findings that might arise to ensure that participants are as informed as possible." PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 6, at 13.

Importantly, however, scholars generally agree that disclosure of an incidental finding “does not transform a research relationship into a clinical one.”<sup>139</sup> Thus, despite the evolving relationship between investigators and participants as a result of the emerging obligation to disclose (at least the potential for) research findings, that relationship should not be treated as identical to the treatment relationship. As both the doctor-patient and investigator-participant relationships continue to shift over time in the wake of technological and other advances and discoveries, the duties that arise under each will also evolve.<sup>140</sup>

#### IV. A CALL FOR A PRIVATE RIGHT OF ACTION FOR INFORMED CONSENT IN RESEARCH, BASED ON THE EVOLVING INVESTIGATOR-PARTICIPANT RELATIONSHIP

Research participants who experience physical or dignitary harms<sup>141</sup> as a result of lack of informed consent still have little recourse. While there is a robust literature focused on the absence of investigator liability for failure to provide informed consent based on concerns regarding information imbalance, bodily integrity, and autonomy,<sup>142</sup> law and policy makers have yet to reach consensus about how or even whether a research participant should have a private right of action for failure to disclose the risks of a research protocol.

Further, the movement to require disclosure of research findings may signal a shift in the right of participants to seek remedies directly from researchers and research institutions who neglect to communicate such information.<sup>143</sup> The assertion that an investigator is obliged to disclose (or offer the research participant the opportunity

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<sup>139</sup> PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 6, at 16. In contrast, however, few have expressed concern that requiring return of results could “turn the research enterprise into a proxy clinical enterprise.” *Id.* at 91 (quoting Robert C. Green’s presentation to the Presidential Commission).

<sup>140</sup> In fact, research involving genetic or other biological samples may signal the development of a more tenuous investigator-participant relationship than in the past. See Valerie G. Koch, *PGTandMe: Social Networking-Based Genetic Testing and the Evolving Research Model*, 22 HEALTH MATRIX 33 (2012). Thus, rather than opening the door to a private right of action based on a more robust duty of care, the proliferation of research involving biological materials may, instead, diminish the duty investigators have to their participants.

<sup>141</sup> Dignitary harms are “caused by conduct that overrides patients’ autonomy, treats them as less than human, and denigrates them as human beings.” Dena S. Davis, *The Ambiguous Effects of Tort Law on Bioethics: The Case of Doctor-Patient Communications*, 21 J. CLIN. ETHICS 264, 265 (2010).

<sup>142</sup> See BERG ET AL., *supra* note 4; Morreim, *supra* note 4, at 63; Mello, Studdert & Brennan, *supra* note 4, at 40; Jansson, *supra* note 4, at 235; Pike, *supra* note 4, at 7.

<sup>143</sup> See *supra* Section III.

to receive) findings that are *secondary* to the research protocol is at odds with the lack of obligation to disclose the *primary* risks of the research protocol itself. As the hypotheticals at the outset of this Article demonstrate, if society is to impose an affirmative obligation on investigators to return findings unrelated to the research protocol, for which failure to do so could result in tort liability, it seems incongruous that research participants should not be able to recover for failure to meet the lesser obligation to disclose the risks of the study in which the subject is actually participating.

In light of the evolving research model, as represented by the collection, retention, and testing of biological samples or use of medical imaging, the traditional distinction between recovering for lack of informed consent in the treatment and research contexts is becoming less justifiable.

#### A. *Autonomy as the Underlying Principle*

Each duty at issue in the present analysis—(1) the duty of the doctor to the patient to provide informed consent, (2) the duty of the investigator to the participant to provide informed consent, and (3) the duty of the investigator to disclose incidental or secondary findings (or the possibility thereof) to participants—is premised on the principle of autonomy.<sup>144</sup> For purposes of this discussion, autonomy encompasses the ability to choose to receive information about oneself and to make and carry out informed decisions based on that knowledge.<sup>145</sup>

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<sup>144</sup> This Article does not attempt to dissect or examine the autonomy principle in significant depth. For such analysis, see IMMANUEL KANT, *ETHICAL PHILOSOPHY* (James W. Ellington trans., 1983); JOHN STUART MILL, *ON LIBERTY* (Elizabeth Rappaport ed., 1978). For discussions of the principle of autonomy in the medical context, see KATZ, *supra* note 14; Shultz, *supra* note 12; Alexander McCall Smith, *Beyond Autonomy*, 14 J. CONTEMP. HEALTH L. & POL'Y 23 (1997); Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 IND. L.J. 727 (1993).

<sup>145</sup> It has been argued that the principle of autonomy has two different meanings, each of which is invoked in different contexts to serve different purposes. The first, liberal individualism, is “the idea that each person has a right to make his or her own decisions about matters that affect that person in important ways and to act to effectuate those decisions.” Roger B. Dworkin, *Getting What We Should from Doctors: Rethinking Patient Autonomy and the Doctor-Patient Relationship*, 13 HEALTH MATRIX 235, 238 (2003). The second, physical essentialism, “is the view that one is entitled to be let alone, especially to have one’s body let alone.” *Id.* Similarly, Mark S. Stein and Julian Savulescu distinguish between two conceptions of autonomy: the “liberal conception” and the “libertarian conception” of autonomy. Mark S. Stein & Julian Savulescu, *Welfare versus Autonomy in Human Subjects Research*, 38 FLA. ST. U. L. REV. 303, 308 (2011). These two conceptions do not directly map onto the two categories that Dworkin describes, although one could engage in a useful comparison. Important to this analysis, Stein and Savulescu explain, “liberal autonomy will not honor a person’s

For one, autonomy is consistently invoked as the operative principle for informed consent in the treatment context. For example, Marshall Kapp explains, the “ethical precept [of individual autonomy] has been transformed slowly but steadily in the United States into the enforceable legal doctrine of informed consent.”<sup>146</sup> Peter Shuck asserts that “[t]he most fundamental normative argument in favor of requiring health care providers to obtain patients’ informed consent to medical treatments proceeds from the principle of autonomy—the notion that each mature individual has a right to make the basic choices that affect her life prospects.”<sup>147</sup>

Second, the federal regulations governing human subjects research also rely on the autonomy principle in its informed consent requirements.<sup>148</sup> As research evolves to focus more on human biological materials than on physical interventions, harmed research participants are less able to rely on the traditional claim for battery.<sup>149</sup> As research shifts to focus on previously collected biological

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decision to be a subject in an experiment unless that decision is made with full information, under conditions that conduce to full understanding and authentic choice.” In contrast, “[l]ibertarianism respects the actual choices of people, whether or not those choices are made with full information,” and thus, “libertarian autonomy cannot easily endorse the requirement of informed consent.” *Id.* at 309. Regarding this latter definition, scholars have maintained that one’s right to make decisions about oneself depends on the relative privacy of the choice, and the most private of choices relates to those concerning one’s own body. Peter H. Shuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 924 (1994). However, the first definition is most frequently invoked by courts and scholars in the context of informed consent in both the treatment (Dworkin, at 245) and research (Stein & Savulescu, *supra* note 145, at 308) contexts and in arguments in support of disclosing research findings. Compounding the obligation of investigators to participants is the broader notion that “investigators have ‘ancillary care’ obligations to their study participants.” Dal-Ré et al., *supra* note 113, at 2. Notably, commentators have addressed the foundation of ancillary care in the principle of autonomy, based on the relationship between the investigator and research participant.

<sup>146</sup> Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 28 J. LEGAL MED. 91, 91 (2007).

<sup>147</sup> Shuck, *supra* note 145, at 924; *see also* George P. Smith II, *The Vagaries of Informed Consent*, 1 IND. HEALTH L. REV. 109 (2004). Evelyn Tenebaum states, “[t]he purpose of informed consent laws is to ensure that patients receive sufficient information about the risks and alternatives of medical procedures to make their own health care decisions based on their personal values, preferences, and priorities.” Evelyn Tenebaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697 (2012).

<sup>148</sup> Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 610 (2007) (“The common rule’s informed consent requirement is designed to supply research subjects with all the information they need to perform an autonomous risk-benefit analysis.”).

<sup>149</sup> *See supra* Part I.A.



specimens,<sup>150</sup> donors' continued status as research participants becomes less certain,<sup>151</sup> further implicating participants' autonomy interests and privacy rights.<sup>152</sup>

Third, supporters of a duty to return research findings often rely upon the principles of respect for persons and autonomy, describing the participants' "presumptive entitlement" to information about themselves.<sup>153</sup> In one study, patients and public groups "emphasized having 'the power' to choose disclosure or not, and that patients no longer accept medical paternalism."<sup>154</sup>

Thus, the autonomy principle upon which calls to disclose research findings rely is the same as that upon which informed consent—in both the treatment and research contexts—is premised. In fact, some scholars have sought to explicitly link informed consent at the outset of research to disclosure of research findings in order to "ensure that the research process as a whole honors the notion of respect for persons upon which human research subjects protections are premised."<sup>155</sup> Further, technological advances in genomics may advance "a more thoroughgoing respect for persons than was possible when current policies governing human subject research were developed."<sup>156</sup> Thus, application of the autonomy principle to justify return of research results but not to support informed consent to research is both incoherent and incongruous.<sup>157</sup>

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<sup>150</sup> Existing policy and current academic literature acknowledges that the federal rules and regulations governing informed consent for research with human subjects also apply to most research with biospecimens, except in some limited conditions. David Wendler, *One Time General Consent for Research on Biological Samples*, 332(7540) BRIT. MED. J. 544 (2006); Marshall B. Kapp, *Ethical and Legal Issues in Research Involving Human Subjects: Do You Want a Piece of Me?*, 59 J. CLIN. PATHOL. 335–39 (2006); Barbara J. Evans and Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J. LEG. MED. 119 (2006).

<sup>151</sup> See Clayton & McGuire, *supra* note 94, at 473.

<sup>152</sup> David Magnus & Mildred K. Cho, *Issues in Oocyte Donation for Stem Cell Research*, 308(5729) SCIENCE 1747 (2005); Geoff Lomax & Steve Peckman, *Stem Cell Policy Exceptionalism: Proceed with Caution*, 8 STEM CELL REV. AND REP. 299 (2011).

<sup>153</sup> Shalowitz & Miller, *supra* note 116, at 738; see also Wolf, Paradise & Caga-anan, *supra* note 30, at 367; Dena S. Davis, *Opportunistic Testing: The Death of Informed Consent?*, 23 HEALTH MATRIX 35 (2013).

<sup>154</sup> Anne Townsend et al., *Paternalism and the ACMG Recommendations on Genomic Incidental Findings: Patients Seen But Not Heard*, 15 GENETICS IN MED. 751, 752 (2013).

<sup>155</sup> Debra J.H. Mathews & Leila Jamal, *Revisiting Respect for Persons in Genomic Research*, 5 GENES 1 (2014).

<sup>156</sup> *Id.* at 2.

<sup>157</sup> See Kapp, *supra* note 146, at 93 ("It is erroneous, even counterproductive, to attempt to pick and choose among different categories of health care choices and then apply the autonomy principle selectively.").

Regardless of whether informed consent serves the interest of patient or participant autonomy in actuality, informed consent in the research context relies on the same operative theoretical principles of autonomy and respect for persons as informed consent in the treatment context.<sup>158</sup> Sharing these underlying principles further supports treating the duties of both physicians and investigators similarly. This Article proposes that, based on the consistently-applied principle of not treating persons as mere means to an end, research participants should have access to a private right of action against investigators who fail to provide informed consent, similar to the access patients have to a private right of action against doctors who do the same. The establishment of a method to compensate research participants for injuries sustained as a result of participating in a study is the rational, just approach.<sup>159</sup>

*B. The Standard of Care for a Private Right of Action for Informed Consent in Research*

However, the standard of care for such a private right of action for informed consent in research should not be identical to the standard for informed consent in treatment. Although research participants should have a right to recover for failures of informed consent, courts should consider applying a new (or at least modified) approach—one other than medical malpractice or ordinary

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<sup>158</sup> An analysis of the advisability of continuing to rely on “autonomy rhetoric” in the medical context is beyond the scope of this Article. For a discussion of the concept of autonomy, see Dworkin, *supra* note 145, at 247 and Edmund D. Pellegrino, *Patient & Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 J. CONTEMP. HEALTH L. & POL’Y 47 (1994).

<sup>159</sup> Some have called for the establishment of a “distinct dignitary tort” for “serious deficiencies of informed consent,” in both medical care and research. Morreim, *supra* note 4, at 73–74 (citing Joseph Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683, 691 (1975); Joan Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 270–72 (1999); Nancy Levit, *Ethereal Torts*, 61 GEO WASH. L. REV. 136, 150–51 (1992); Shultz, *supra* note 12, at 291–92; Alan Meisel, *A ‘Dignitary Tort’ as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 L., MED. HEALTH CARE 210, 210–18 (1988); Grant H. Morris, *supra* note 20, at 322; Alan Weisbard, *Informed Consent: The Law’s Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 763 (1986). In *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL’Y 1, 74 (2003), E. Haavi Morreim notes:

[B]ecause standard informed consent doctrine usually limits recovery to cases featuring a physical or other separate injury, it can fail to honor human autonomy in cases where someone’s right to choose has been abused without demonstrable physical damage. If this is a problem in ordinary medicine, it is even more so in the research setting.

negligence—in its analysis.<sup>160</sup> For one, simple negligence claims are inappropriate for remedying harms that occur in the research context.<sup>161</sup> The *Ande v. Rock* opinion is representative of this concern.<sup>162</sup> By finding that no special relationship existed between the investigators and the participant’s family, the court held that the researchers owed no duties to the plaintiffs beyond those required under ordinary negligence.<sup>163</sup> The case demonstrates the problems that arise when courts find research to be “nothing more than ordinary conduct”—and the need to recognize that “[r]esearchers have many duties that go well beyond those of ordinary citizens in the affairs of daily life.”<sup>164</sup>

Second, although it may be argued that justice requires that research subjects be treated like patients, with the attendant rights and remedies, it does not necessarily follow that the same standards of care be applied to participants in clinical trials as to patients in the clinical setting.<sup>165</sup> Requiring a different—and probably heightened<sup>166</sup>—standard for disclosure of the risks of research (compared to treatment) is necessary for a number of reasons. Despite the similarities between treatment and research, approaching the two as equivalents would be “generous but flawed.”<sup>167</sup> The simplest reason for

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<sup>160</sup> Morreim, *supra* note 4, at 32. For example, the author recommends that “conduct that is distinctive to research should be litigated under a research-focused standard of care based on defects in the protocol, failures to adhere to the protocol, breaches of research-specific informed consent, and the like.” *Id.* at 41; *see also* Coleman, *supra* note 3, at 403.

<sup>161</sup> Importantly, because there are significant differences between treatment and research, there are also “major differences among research injuries, medical malpractice, and ordinary negligence.” Morreim, *supra* note 4, at 30. The author notes:

Across this spectrum, the message is not that research injuries are somehow worse (or better) than medical malpractice, or that we need to augment (or diminish) the available causes of action against research errors. The message is simply that research is different, that courts need to be more knowledgeable and to think more clearly if they are to build an adequate foundation by which to guide conduct in this increasingly important realm.

*Id.* at 32.

<sup>162</sup> 647 N.W. 2d 265 (WI Ct. App. 2002). *See supra* Section III.

<sup>163</sup> 647 N.W. 2d 265 (WI Ct. App. 2002).

<sup>164</sup> Morreim, *supra* note 4, at 30.

<sup>165</sup> Dal-Ré et al., *supra* note 113; Kathleen Cranley Glass & Duff Waring, *The Physician/Investigator’s Obligation to Patients Participating in Research: The Case of Placebo Controlled Trials*, 33 J. L. MED & ETHICS 575 (2005).

<sup>166</sup> Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J. L. & MED. 361, 379 (2002); *Whitlock v. Duke Univ.*, 829 F.2d 1340 (4th Cir. 1987).

<sup>167</sup> Richardson & Belsky, *supra* note 94, at 26.

a distinction between the standards of care is that researchers are not always physicians.<sup>168</sup> Where the investigator is a physician, conflating the “roles of personal physician and clinical researcher . . . threatens to exacerbate the therapeutic misconception.”<sup>169</sup> More fundamentally (and as discussed above), the primary goals of treatment and research are distinct: the former is focused on the care and health of the individual patient, while the latter aims to produce generalizable knowledge.<sup>170</sup> Moreover, in contrast to the decision to pursue therapeutic treatment (which generally is based on a desire to maintain or improve one’s own health or well-being), the decision to participate in a research protocol is “highly individual”<sup>171</sup> and may be based on a variety or combination of reasons.<sup>172</sup>

Historically, when determining the standard for disclosure in the treatment context, courts considered what a *reasonable physician* would have disclosed under the circumstances.<sup>173</sup> However, this “professional standard” of informed consent has been replaced in at least half of the states by the *reasonable patient* standard enunciated in *Canterbury v. Spence*<sup>174</sup> because of the former’s “excessive paternalism and the effective immunity that it granted to defendants.”<sup>175</sup> In contrast to tort

<sup>168</sup> Richardson & Belsky, *supra* note 94, at 26.

<sup>169</sup> Richardson & Belsky, *supra* note 94, at 26. For a full explanation and analysis of the therapeutic misconception, see Paul S. Appelbaum et al., *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUMAN RESEARCH 1 (2004); Paul S. Appelbaum et al., *Corrections and Clarifications*, 26 IRB: ETHICS & HUMAN RESEARCH 18 (2004).

<sup>170</sup> Coleman, *supra* note 3; BERG ET AL., *supra* note 4, at 281; Gordon, *supra* note 55.

<sup>171</sup> E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J. L. MED. & ETHICS 474, 479 (2004) (explaining why the two prevailing standards of care—the physician-based standard and the reasonable-patient standard—for physicians’ duty of disclosure would be inappropriate in the research context).

<sup>172</sup> *Id.* (“People can have a wide variety of reasons for entering research, from altruism to financial gain to a desperate, last-ditch hope for cure.”).

<sup>173</sup> See Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, *supra* note 166, at 367 (citing *Craig v. Borcicky*, 557 So. 2d 1253, 1258 (Ala. 1990); *Fuller v. Starnes*, 597 S.W.2d 88, 89-90 (Ark. 1980); *Shabinaw v. Brown*, 963 P.2d 1184, 1188-94 (Idaho 1998); *Culbertson v. Mernitz*, 602 N.E.2d 98, 101, 103-04 (Ind. 1992); *Ziegert v. South Chicago Community Hosp.*, 425 N.E.2d 450, 458-59 (Ill. App. Ct. 1981); *Woolley v. Henderson*, 418 A.2d 1123, 1128-31 (Me. 1980); *Paul v. Lee*, 568 N.W.2d 510, 514-16 (Mich. 1997); *Robinson v. Bleicher*, 559 N.W.2d 473, 478 (Neb. 1997); *Hook v. Rothstein*, 316 S.E.2d 690, 695-98 (S.C. Ct. App. 1984); *Weber v. McCoy*, 950 P.2d 548, 552 (Wyo. 1997)).

<sup>174</sup> Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J. L. & MED. 429, 430 (2006).

<sup>175</sup> See, e.g., Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, *supra* note 166, at 367 (citing *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Cobbs v. Grant*, 502 P.2d 1, 9-11 (Cal. 1972); *Largey v. Rothman*,

liability for failure to provide informed consent in the treatment context—in which jurisdictions are split on the standard for what information qualifies as material information for disclosure—tort liability for failure to provide informed consent in the research context should require the establishment of a particular and carefully crafted standard of disclosure. Between these two standards, the reasonable patient standard is likely a more appropriate approximation or model of the standard of informed consent for research (in other words, a reasonable participant standard).

In determining what this reasonable participant standard should look like, one can look to (1) the standards set forth under federal regulations and (2) those historically relied upon in the doctor-patient relationship context. Further, the disclosure standard in research could include both an objective and a “subjective element in deference to individuals’ varying needs for personally important information, as by inviting prospective enrollees to ask questions.”<sup>176</sup>

Thus, an appropriate baseline standard for disclosure of the risks of research to participants is most likely one commensurate with the disclosure requirements under the federal rules,<sup>177</sup> which “require an array of facts to be disclosed, such as the purposes, duration and procedures of the research; any reasonably foreseeable risks or discomforts; potential benefits to the enrollee or to others; available alternatives to the research trial; and other specified information.”<sup>178</sup> However, the current regulatory requirements for disclosure in research may be insufficient to truly protect individuals who are harmed as a result of investigators providing inadequate informed consent. Courts should beware that the legal “floor” for acceptable behavior may become the ethical standard for disclosure in research, thereby undercutting participants’ rights to autonomy and respect.<sup>179</sup> Disclosure standards should be crafted to address the significant and distinct dignitary harms that can occur as a result of failure to disclose

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540 A.2d 504, 508–09 (N.J. 1988)).

<sup>176</sup> Morreim, *supra* note 171, at 479.

<sup>177</sup> See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2152 (2000); see also Richard Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1253–54 (1996); Jansson, *supra* note 4, at 245; Mastroianni, *supra* note 76, at 420 (referring to the “comprehensiveness and specificity of the regulatory requirements for informed consent”).

<sup>178</sup> Morreim, *supra* note 4, at 66. See *Grimes v. Kennedy Krieger Institute*, 782 A.2d 807, 849 (Md. 2001) (emphasizing federal regulations as a source of informed consent duties); *Daum v. SpineCare Med. Group, Inc.*, 52 Cal. App. 4th 1285 (1997) (deriving the standard of care for informed consent from the federal regulations).

<sup>179</sup> Davis, *supra* note 141, at 270.

the risks of a research protocol.<sup>180</sup>

C. *Some Final Thoughts and Caveats*

This Article would be deficient if it failed to address the argument that the establishment of a private right of action for failure to provide informed consent in the research context could negatively impact the research enterprise as a whole.<sup>181</sup> Commentators have recognized that requiring disclosure of research results to participants could give rise to increased investigator liability.<sup>182</sup> Despite its ability to compensate injured research participants, allowing subjects a private right of action “has potentially undesirable ramifications for research oversight because it is likely to drive IRBs toward a more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress.”<sup>183</sup> Thus, the “threat of tort liability could paralyze IRBs and could have a significant chilling effect on clinical research.”<sup>184</sup>

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<sup>180</sup> It has also been suggested that there is (or will be) an identifiable and distinct standard of care for return of research findings. For example, some have argued that it would be appropriate “to apply a standard-of-care list of genes for which to actively seek pathogenic variants in clinical research,” (Dal-Ré et al., *supra* note 113) equivalent to the American College of Medical Genetics and Genomics’s (ACMG) recommendations for management of incidental genomic findings obtained in clinical practice. Robert C. Green et al., *supra* note 117, at 565. The recommendations proposed that clinical genome sequencing laboratories actively seek and report pathogenic variants for 56 genes for 24 conditions for all patients, regardless of patients’ age or expressed desire to receive the information. *Id.* at 570–71. Although the ACMG’s recommendations are controversial (*See, e.g.*, Susan M. Wolf, George J. Annas & Sherman Elias, *Patient Autonomy and Incidental Findings in Clinical Genomics*, 340 *SCIENCE* 1049 (2013); Neil A. Holtzman, *ACMG Recommendations on Incidental Findings are Flawed Scientifically and Ethically*, 15 *GENETICS IN MED.* 750 (2013); Lainie Friedman Ross, Mark A. Rothstein & Ellen Wright Clayton, *Mandatory Extended Searches in All Genome Sequencing: “Incidental Findings,” Patient Autonomy, and Shared Decision Making*, 310 *JAMA* 367 (2013))—in particular because they arguably subvert the principles of autonomy and informed consent by calling for mandatory screening and reporting of gene variants to clinicians and patients (*See* Robert Klitzman, Paul S. Appelbaum & Wendy Chung, *Return of Secondary Genomic Findings vs. Patient Autonomy: Implications for Medical Care*, 310 *JAMA* 369 (2013); Anne Townsend et al., *supra* note 154, at 1–2))—many believe that “it is reasonable to assume that a standard of care will emerge for returning incidental genomic findings to patients receiving WGS/WES in clinical contexts.” Dal-Ré et al., *supra* note 113, at 2.

<sup>181</sup> *See Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992) (“If experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.”).

<sup>182</sup> Clayton & McGuire, *supra* note 94, at 474.

<sup>183</sup> Mello, Studdert & Brennan, *supra* note 4, at 40.

<sup>184</sup> *See* Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 *J. HEALTH CARE L. & POLY* 175, 213 (2004) (citing Richard A.

On the other hand, some maintain that offering the return of findings to research participants may increase public trust in the research enterprise or even increase general awareness of research protocols, thereby leading to more, rather than less, research participation.<sup>185</sup> Moreover, the threat of liability may not have the chilling effect on research that some fear, because the risk of loss of funding or suspension of research is already sufficiently threatening.<sup>186</sup>

Despite these arguments, whether increased liability would lead to a significant decrease in useful and important research has not been reliably determined. Even if allowing a private right of action for lack of informed consent in the research context did disincentivize certain research, this may be an acceptable trade-off for ensuring that research participants are treated with the respect they are increasingly coming to expect and have always deserved.<sup>187</sup> Imposing liability for failure to provide informed consent in the research context would serve the dual purpose of deterring bad behavior by researchers and research institutions and compensating research participants for the physical and dignitary harms suffered as a result of such failure. Further, it sets a standard for disclosure that reflects the rights of research participants and the evolving expectation for shared decision-making in informed consent. Thus, courts and legislatures<sup>188</sup> should pay special attention

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Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1847 (1996)); see also Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1156 (1987).

<sup>185</sup> Fiona Alice Miller et al., *supra* note 118, at 48. See also Shalowitz & Miller, *supra* note 116, at 740.

<sup>186</sup> For example, within a two-year period in the early 2000s, the FDA and OHRP “temporarily shut down research programs in at least seven institutions while they remediated a host of compliance problems.” Barbara A. Noah, *supra* note 184, at 206. See, e.g., Gina Kolata, *Johns Hopkins Death Brings Halt to U.S.-Financed Human Studies*, N.Y. TIMES, July 20, 2001, at A1 (reporting on the suspension of federal research funding to Johns Hopkins due to fact that investigators missed published research reporting serious side effects associated with the investigational compound, and that the university had received 310 million dollars—more federal research funding than any other university).

<sup>187</sup> For a consideration of the balancing between research innovation and the right of informed consent, see Maureen S. Dorney, *Moore v. the Regents of the University of California: Balancing the Need for Biotechnology Innovation Against the Right of Informed Consent*, 5 HIGH TECH. L. J. 333 (1990).

<sup>188</sup> In lieu of developing a private right of action through the courts, state legislatures could establish a statutory tort. Although the most efficacious approach to establishing a private right of action for research—be it statutorily or judicially—is outside the scope of this Article, it is interesting to note that the court in *Wright v. Fred Hutchinson Cancer Research Center* expressly noted that Congress had “contemplated, but ultimately rejected, a statutory mechanism for the compensation of individuals and their families for injuries resulting from their participation in human subjects research.” *Wright*, 269 F. Supp. 2d 1286, at 1290 n.1 (citing S. Rep. No. 93-381, at 90

to balancing the rights of research participants with the interests of furthering valuable research, in order to avoid allowing informed consent to become a protector against liability rather than a protector of prospective participants' rights and welfare. In other words, the standard for disclosure must ensure that the informed consent process protects participants of research, rather than investigators and research institutions against potential liability.

In contemplating tort liability for informed consent in the research context, we would be well served to consider the greater issue of compensation for research-related harms. Although such analysis is beyond the scope of this Article (as is the current regime for tort liability for research-related harms generally), it is important to note the continuing and polarizing debate surrounding this issue, because adopting a national compensation system for all harms that arise as a result of participating in research may obviate the need for a private right of action for informed consent in the research context. Currently, the United States does not require compensation for research related injuries for research participants.<sup>189</sup> Nor is there any indication that the federal government will implement such a system in the foreseeable future. In 2011, the Presidential Commission for the Study of Bioethical Issues, like other commissions and advisory bodies before it, called for the federal government to study the issue of research-related injuries to determine if there is a need for a national system of compensation or treatment for research-related injuries.<sup>190</sup> However, the United States has conspicuously refused to

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(1973)). Moreover, recently proposed revisions by the Department of Health and Human Services (HHS) and the Office of Science and Technology Policy are intended to clarify the extent and scope of the Common Rule. Human Subjects Research Projections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. at 44512 (2011). The Advanced Notice of Proposed Rulemaking (ANPRM) "raises the possibility that in the future contributors will be asked for consent to research on data and samples collected in clinical care, and thus could be asked at that point if they wish to be recontacted in the future about findings of potential clinical importance." Wolf et al., *Managing Incidental Findings*, *supra* note 110, at 372. However, it makes no mention of providing research participants who are harmed due to insufficient informed consent the opportunity to recover from investigators who violate the requirements of the Common Rule.

<sup>189</sup> According to one study, only sixteen percent of academic medical centers in the United States make it a policy to pay for the care of injured subjects. Renuka Munshi & Urmila Thatte, *Compensation for Research Related Injury*, 4 PERSPECTIVES IN CLIN. RESEARCH 61, 66 (2013).

<sup>190</sup> PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *Moral Science: Protecting Participants in Human Subjects Research* (2011), at 8, available at <http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf>. The Commission identified the fact that "previous presidentially appointed bioethics



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sign on to the Declaration of Helsinki—a set of ethical principles regarding human subjects research developed for the medical community—since before the turn of the century. The seventh edition of the Declaration of Helsinki, adopted by the World Medical Association in 2013, added a new general principle: that “[a]ppropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.”<sup>191</sup> Thus, until the United States adopts a compensation system for harms arising as a result of research participation, a private right of action for informed consent is necessary, premised on the evolving relationship between the investigator and research participant.

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commissions and other duly appointed advisory bodies have made similar recommendations regarding compensation or treatment for research-related injuries; yet no clear response by the federal government has been issued.” *Id.* at 70.

<sup>191</sup> *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, available at <http://www.wma.net/en/30publications/10policies/b3/> (last visited Nov. 9, 2014). As a general principle, the Declaration states, “[w]hile the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.” *Id.*