ARTICLES

Genetic Property

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Under U.S. law, there is no property interest in mere facts. But with respect to factual data relating to human genes, a de facto property regime has emerged in all but name. The level of control that individuals have exerted over genetic data exhibits the classic hallmarks of Blackstonian property: the right to exclude, the right to destroy, dead hand control, divisibility, and alienability. This degree of control has arisen through an expansive interpretation of the ethical requirement of informed consent. Notwithstanding the ongoing evolution of federal research regulations that permit some data-based research to proceed without extensive consent requirements, actions sounding in state property law pay little heed to these regulatory procedures. The resulting property-like regime over genetic data has enabled individuals to bring litigation disrupting and even halting valuable biomedical research and leading to the destruction of valuable research resources.

Looking to Calabresi's and Melamed's seminal analysis of property and liability rules, I propose that the property-like treatment of genetic data be replaced by a combination of existing and new regulations of researcher conduct (liability rules) to protect individuals from abusive research practices. This approach would shift the landscape from one in which data-based research cannot occur without the consent of individual research participants to one in which research is presumptively allowed, but researchers face liability for overstepping the bounds of permitted activity.

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INTRODUCTION

> "I would like to think that if somebody does a test on me or my genes, . . . that's mine . . . ."[1]
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> —President Barack Obama (Feb. 2016)

It is axiomatic under U.S. law that no property interest exists in mere facts.[2] Once released into the world, the genie of facts, data, and information cannot be put back into the bottle. They become public goods—in the words of Louis Brandeis, "free as the air to common use."[3] This rule has been applied not only to facts such as the news of the day[4] and sports scores,[5] but also to individual medical and genetic data. In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court held that the sequence of naturally occurring human

1. Julie Hirschfeld Davis, *President Weighs in on Data from Genes*, N.Y. Times, Feb. 25, 2016, at A15.

2. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 344–45 (1991) ("That there can be no valid copyright in facts is universally understood. The most fundamental axiom of copyright law is that '[n]o author may copyright his ideas or the facts he narrates.'"); Int'l News Serv. v. Associated Press, 248 U.S. 215, 234 (1918).

3. *Int'l News Serv.*, 248 U.S. at 250 (Brandeis, J., dissenting).

4. *See id.* at 234.

5. *See* Nat'l Basketball Ass'n v. Motorola, Inc., 105 F.3d 841, 853 (2d Cir. 1997).

DNA was not subject to patent protection.[6] Likewise, in cases including *Moore v. Regents of the University of California*,[7] *Washington University v. Catalona*,[8] and *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,[9] federal courts declined to recognize property interests claimed by individuals in discoveries and information obtained through the analysis of their biological material.

But despite nearly a century of precedent, as well as a succession of failed legislative attempts to establish property rights in information,[10] there has been a recent movement to redefine the traditional understanding of data ownership. Well-intentioned scholars, policymakers, and advocates, motivated by concerns over personal privacy and individual autonomy, have argued for the recognition of property rights in genetic data and other health information[11] to empower individuals to control the exploitation of that information.[12] Others have argued that the recognition of such property interests would facilitate the development of an efficient market for the licensing and usage of health information.[13] Still others support the recognition of property rights in health information, provided

6. 133 S. Ct. 2107, 2111 (2013).

7. 793 P.2d 479, 493 (Cal. 1990).

8. 490 F.3d 667, 673 (8th Cir. 2007).

9. 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003).

10. *See* News Copyright Bill, S. 1728, 48th Cong. (1884); J. H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & CONTEMP. PROBS. 315, 388–95 (2003) (discussing the database protection debate of the 1990s); Peter K. Yu, *The Political Economy of Data Protection*, 84 Chi.-Kent L. Rev. 777, 780–82 (2010) (same).

11. When discussed in the literature, the concept of personal health information includes a wide range of items including medical records, test results, physical tissue samples, and aggregated data concerning an individual's family, community, ethnicity, and other demographic information. For a discussion of some of these data types, see Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 90–92 (2011).

12. The literature concerning information privacy and the ownership of personal data is extensive. *See, e.g.*, LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 142–63 (1999) (proposing a property-based framework to protect personal online privacy); Julie E. Cohen, *Examined Lives: Informational Privacy and the Subject as Object*, 52 STAN. L. REV. 1373, 1379 (2000); Evans, *supra* note 11, at 73 n.26 (citing several patient advocates and works in the popular press that have called for patient ownership of health data); Jessica Litman, *Information Privacy/Information Property*, 52 STAN. L. REV. 1283, 1289–95 (2000); Patricia Mell, *Seeking Shade in a Land of Perpetual Sunlight: Privacy as Property in the Electronic Wilderness*, 11 BERKELEY TECH. L.J. 1, 26–41 (1996); Paul M. Schwartz, *Property, Privacy, and Personal Data*, 117 HARV. L. REV. 2056, 2056 (2004) (proposing a five-part framework defining rights in personal information).

13. Mark A. Hall, *Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records*, 95 IOWA L. REV. 631, 659–63 (2010); Mark A. Hall & Kevin A. Schulman, *Ownership of Medical Information*, 301 J. AM. MED. ASS'N 1282, 1284 (2009) (urging the adoption of "clear and adaptable laws" to enable patients to "assign economic value to the access, control, and use of the medical information contained in electronic health record networks"); *see also* Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, *in* GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 31, 50 (Mark A. Rothstein ed., 1997) (allowing individuals to sell their genetic information will make them equal participants in the market, avoiding exploitation by others); David F. Partlett, *Misuse of Genetic Information: The Common Law and Professionals' Liability*, 42 WASHBURN L.J. 489, 497 (2003) ("If the genetic information is property, it can presumably be sold, leading to a market in the information.").

these rights are controlled by the state in furtherance of the public good,[14] and others have turned to property theory as a means to account for the related interests that family members share in their collective DNA.[15]

On the other hand, some view the propertization of genetic data and other health information as undesirable or unnecessary. Jane Baron, for example, argues that property rights, and property doctrine more broadly, are inapposite to the description and protection of personal interests in health information.[16] Sonia Suter resists the application of property labels to genetic information based on concerns over commodification and the inability of property law to redress dignitary and trust-based harms.[17] Barbara Evans has observed that many protections sought to be achieved through property law already exist in the regulatory frameworks that govern medical records and research and that preferable solutions should instead seek to address critical infrastructure and data management issues and to empower individuals to collaborate through consumer-driven information commons.[18] And the OECD has suggested that assigning ownership of health-related data to individuals would limit the ability of data analysts to make the greatest social utilization of that data and fail to address most of the problems that such ownership seeks to solve.[19]

I argue, however, that the debate over legal recognition of a personal property interest in health information, and genetic data specifically, has largely been

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14. Marc A. Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 AM. J.L. & MED. 586, 589 (2010) (arguing for public ownership and stewardship of health databases); *see also* G. Haddow et al., *Tackling Community Concerns About Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal*, 62 SOC. SCI. & MED. 272, 276–77 (2007) (finding that many survey respondents believed that a national Scottish genetic database (Generation Scotland) should be publicly owned or controlled by public servants).

15. *See, e.g.*, Laura Maria Franciosi & Attilio Guarneri, *The Protection of Genetic Identity*, 1 J. CIV. L. STUD. 139, 186 (2008) ("[P]roperty laws may better serve as a paradigm to ensure that a greater level of protection is provided for information that belongs to all of the individuals involved."); Natalie Ram, *DNA by the Entirety*, 115 COLUM. L. REV. 873, 906–10 (2015) (proposing that DNA be owned through a "tenancy by the entirety" joint ownership model in order to account for the interests of related family members).

16. *See* Jane B. Baron, *Property as Control: The Case of Information*, 18 MICH. TELECOMM. & TECH. L. REV. 367, 370, 372–90 (2012) (arguing that property law concepts such as alienability and in rem treatment are difficult to translate to the realm of personal health data).

17. Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 798–811 (2004). Suter follows in the tradition of seminal work by Margaret Jane Radin, arguing that certain things such as human blood and infants, as a general philosophical principal, should never be alienable. *See generally* Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987).

18. Barbara J. Evans, *Barbarians at the Gate: Consumer-Driven Health Data Commons and the Transformation of Citizen Science*, 42 AM. J.L. & MED. (forthcoming 2016); Evans, *supra* note 11, at 82; Barbara J. Evans, *Would Patient Ownership of Health Data Improve Confidentiality?*, 14 AM. MED. ASS'N J. ETHICS 724, 728 (2012) ("There are few discernible differences between the level of confidentiality patients would enjoy if they owned their data and biospecimens and what they presently have under the HIPAA Privacy Rule and the Common Rule.").

19. OECD, DATA-DRIVEN INNOVATION: BIG DATA FOR GROWTH AND WELL-BEING 195–97 (2015) (identifying numerous possible candidates for data ownership and concluding that ownership itself is an inapt construct for data).

overtaken by events. Among members of the public, there is already a widespread belief that individuals "own" their personal data.[20] President Barack Obama echoed this belief in a recent speech promoting biomedical research. As reported by the *New York Times*, the President expressed concern over "understanding who owns the data" that will be collected under the proposed Precision Medicine Initiative (PMI).[21] His view, which seems to reflect increasing public sentiment, is that "if somebody does a test on me or my genes, . . . that's mine."[22]

In support of these popular perceptions, a handful of states have already enacted laws purporting to grant individuals ownership of their genetic information.[23] But more importantly, even without the benefit of specific legislation, a de facto common law property regime has emerged in all but name with respect to human genetic data. As a result, individuals have brought litigation asserting a growing degree of control over the use of data that is obtained from their genetic material, hindering ongoing scientific research and causing the destruction of valuable research resources.[24]

The means by which this excessive degree of control has crept into the research enterprise is an increasingly expansive view of the doctrine of informed consent, which permeates federal regulations governing human subjects research.[25] The doctrine of informed consent, which took its current form in response to the revelation of serious research abuses both during and after World War II,[26] offers necessary protections to the human subjects of medical experimentation. But this doctrine has been expanded far beyond its original

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20. *See, e.g.*, Jennifer Couzin-Frankel, *DNA Returned to Tribe, Raising Questions About Consent*, 328 SCIENCE 558, 558 (2010) (quoting Kimberly TallBear of the University of California, Berkeley as saying "[r]esearch subjects need to have some ability to assert their property interest in their own biological samples"); Evans, *supra* note 11, at 73 & n.26 (citing numerous sources); Mark A. Rothstein, *Ethical Issues in Big Data Health Research*, 43 J.L. MED. & ETHICS 425, 427 (2015) ("[M]any individuals strongly believe that their biological specimens and health records 'belong to them.'"); Leslie E. Wolf, *Biology & Genetics: Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 103 (recommending recognition of "donor control over the research use of materials, even though this right of control is not fully recognized in the court opinions and in the federal regulations"); Richard H. Thaler, *Show Us the Data. (It's Ours, After All.)*, N.Y. TIMES, Apr. 23, 2011, at BU4.

21. Davis, *supra* note 1; *see infra* notes 31–32.

22. Davis, *supra* note 1.

23. *See* Anya E.R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOK. L. REV. 175, 195–98 (2013) (discussing statutory enactments in Alaska, Colorado, Georgia, Louisiana, and Florida).

24. *See, e.g.*, Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063, 1066, 1073 (Ariz. Ct. App. 2008) (claiming $50 million in damages and leading to the return of tribal DNA samples and discontinuation of research programs); Beleno v. Lakey, Order, No. SA-09-CA-188-FB (W.D. Tex. Sept. 17, 2009) (leading to the destruction of more than five million infant blood spot samples in Texas); *see also infra* Section II.A.1.

25. *See infra* Section I.B (discussing the current legal framework for data protection under the Common Rule, HIPAA Privacy Rule and other regulatory schemes).

26. *See infra* Section I.A (discussing the historical origins of the informed consent doctrine for medical research in postwar prosecution of Nazi war crimes and subsequent revelations).

contours to create what I refer to as "propertizing consent." With propertizing consent, the permission sought from an individual to undergo a medical procedure invests that individual with a property-like interest in the resulting data. As a result, contrary to a century of legal precedent,[27] genetic information has taken on many of the attributes of personal property.

In this Article, I argue that propertizing consent, and the regulation of data-based research under a framework rooted in consent, inappropriately grants individuals excessive and inappropriate control over genetic data. In this regard, I join the many scholars and policymakers who have warned that too much individual control over personal health information may stymie socially valuable biomedical research.[28] The proliferation of individual ownership claims to the public corpus of human genetic information could result in what Michael Heller and Rebecca Eisenberg have famously termed a "tragedy of the anticommons."[29] In the Heller–Eisenberg model, multiple ownership claims (patents, in their example) make it increasingly difficult to conduct research, either because rights owners are unwilling to grant licenses on reasonable terms or because the sheer number of rights holders make it impractical or cost-prohibitive for researchers to procure the necessary rights.[30]

This issue is particularly salient today. In early 2015, the Obama Administration announced the launch of the Precision Medicine Initiative (PMI), an ambitious federal research program that is intended to collect and analyze genetic data from approximately one million Americans.[31] The PMI will seek to improve scientific understanding of disease genetics and facilitate the develop-

27. *See supra* notes 6–9 and accompanying text.

28. *See, e.g.*, INST. OF MED., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 31 (Sharyl J. Nass et al. eds., 2009) (concluding that "the [current] HIPAA Privacy Rule impedes important health research"); OECD, *supra* note 19, at 196 (nonownership structures "may be more effective in maximising welfare while still providing sufficient incentive for the production and release of data").

29. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998). This phrase is a variation on Garrett Hardin's "tragedy of the commons." Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968).

30. The scenario is based on Heller's earlier work on fragmentation of ownership rights in post-Soviet retail space arrangements. Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998). Reichman and Uhlir extend this reasoning to propertized data. Reichman & Uhlir, *supra* note 10, at 402–08; *see also* Rodwin, *supra* note 14, at 606 (recognizing anticommons problems both at the level of data holders and individual patients). *But see* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 985–86, 1020 (2005) (arguing that the public commons model incorrectly assumes that the commons for biomedical science is "finite and congested," thus overstating the value of a commons approach); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001) (rebutting the commons-based arguments posited by Rai and Eisenberg).

31. President Barack Obama, *State of the Union Address* (Jan. 20, 2015) ("[T]onight, I'm launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes, and to give all of us access to the personalized information we need to keep ourselves and our families healthier.").

ment of therapies calibrated to individual genetic profiles.[32] The program will build upon several decades of data-based genetic research, which have already resulted in major advances in scientific knowledge, disease diagnosis, and preventative care.[33]

The PMI, if it is to deliver on its ambitious promise, will require an unprecedented quantity of human DNA from individuals across all age brackets, ethnic groups, and socioeconomic strata.[34] In order to make critical discoveries, researchers from around the world will need to access, recombine, search, and manipulate this data in whatever manner is most promising.[35] If they cannot, and if individuals retain the right to withhold, remove, recall, constrain, or destroy genetic data once it enters the research pool, then the entire scientific enterprise represented by projects such as the PMI will be jeopardized. As the court cautioned in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the recognition of personal property rights in genetic data "would cripple medical research."[36]

Supporters of existing and proposed federal regulations governing biomedical research[37] may argue that various exceptions and mechanisms already exist to permit data-based research without the informed consent of every research participant.[38] But these regulations start from the flawed premise that consent is required to conduct research that uses data collected from individuals. This approach needlessly concedes an individual's property-like control over data

32. *See About the Precision Medicine Initiative Cohort Program*, NAT'L INST. HEALTH, https://www.nih.gov/precision-medicine-initiative-cohort-program [https://perma.cc/7XR7-2SZG] ("The [PMI] program will seek to extend precision medicine's success to many diseases, including common diseases such as diabetes, heart disease, Alzheimer's, obesity, and mental illnesses like depression, bipolar disorder, and schizophrenia, as well as rare diseases.").

33. *See, e.g.*, INST. OF MED., *supra* note 28, at 114–16 (listing numerous health advances achieved through data-driven research); Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 NEW ENGL. J. MED. 793, 793–794 (2015) (describing recent advances enabled by genetic research); Eric S. Lander, *Cutting the Gordian Helix—Regulating Genomic Testing in the Era of Precision Medicine*, 372 NEW ENGL. J. MED. 1185, 1185 (2015) (indicating that more than 3,600 specific disease-associated genes and 4,000 genetic markers for more common diseases have been identified to date).

34. Dr. Francis Collins, the Director of the U.S. National Institutes of Health, estimates that full genetic data is currently available for between 10,000 and 20,000 individuals. Thomas M. Burton, Jonathan D. Rockoff & Ron Winslow, *Obama Announces $215 Million Precision-Medicine Genetic Plan*, WALL ST. J. (Jan. 30, 2015), http://www.wsj.com/articles/obama-to-lay-out-215-million-precision-medicine-plan-1422615602 [https://perma.cc/Y97F-79TP].

35. *See* Collins & Varmus, *supra* note 33, at 794 ("Qualified researchers from many organizations will, with appropriate protection of patient confidentiality, have access to the cohort's data, so that the world's brightest scientific and clinical minds can contribute insights and analysis."); *cf.* Brenda M. Simon & Ted M. Sichelman, *Data-Generating Patents*, 111 NW. L. REV. (forthcoming 2017) (discussing the significant amount of valuable genetic data generated and commercialized by private sector firms such as Myriad Genetics).

36. 264 F. Supp. 2d 1064, 1076 (S.D. Fla. 2003).

37. *See infra* note 74 and accompanying text (discussing the 2015 Notice of Proposed Rulemaking issued by fifteen federal research-funding agencies).

38. *See infra* Sections II.B, II.C, and II.E.

and then proceeds to erect a labyrinthine set of exceptions to enable useful research in the face of this construct.

What's more, many have questioned whether the existing consent framework achieves its goals in the context of genetic research because the consent obtained from individuals is often pro forma and seldom truly informed.[39] And many of the exceptions permitting data-based research depend on the use of "deidentified" data that is stripped of all characteristics linking it back to an individual,[40] a level of protection viewed by many researchers as both impossible to achieve and undesirable for understanding the medical and physiological significance of that data.[41]

Federal research regulations also only apply to research that is funded or overseen by the federal government, and do not expressly apply to research funded by state or local governments, philanthropic organizations, biotechnology firms, and online services such as Facebook and Google.[42] Finally, although federal regulations impose administrative requirements on researchers, potentially affecting their ability to obtain government funding or regulatory approvals, these regulations do not lessen the force of state common law rights of research participants. Thus, even when researchers faithfully comply with administrative and institutional requirements regarding informed consent, as they arguably did in the cases discussed in Section II.A.1, such compliance does not insulate their research from common law property or tort claims that may be asserted by aggrieved individuals or groups.[43] For all of these reasons, relying on federal research regulations to ensure that valuable biomedical research can continue in the face of increasing common law property claims is both shortsighted and inadequate.

In contrast, this Article proposes to eliminate the property-like character of genetic data conferred by informed consent[44] and to replace it with a liability rule system for the governance of genetic research. Guido Calabresi and Doug Melamed first elucidated the distinction between property and liability rules in a seminal 1972 law review article.[45] Property rules, they explained, permit the holder of a right (a property interest) to prevent others from encroaching on the enjoyment of that right, just as a landowner may, under some circumstances, prevent a factory from discharging pollutants that reduce the value of his land.[46]

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39. *See infra* notes 172–75 and accompanying text.

40. *See infra* Section II.C.

41. *See infra* notes 206–10 and accompanying text.

42. *See infra* notes 178–82 and accompanying text.

43. *See infra* Section II.E.

44. This Article does not attempt to address the companion question of property rights in human tissue, organs, and body parts. This question is fraught with legal complexities and dispute, and has been the subject of an extensive literature. *See, e.g.*, LORI B. ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE (2001).

45. Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972).

46. *See id.* at 1105–06, 1116–18.

Liability rules, on the other hand, do not grant an a priori right to prevent an encroachment, but do provide the aggrieved party with a legal remedy (usually damages) if such an encroachment occurs (that is, allowing the land owner to recover monetary damages as compensation for the factory's pollution).[47]

Shifting the regulation of data-based research from a property to a liability regime[48] would move away from a system in which research cannot occur without the consent of individual research participants, to one in which research is presumptively permitted, but researchers face liability for overstepping the bounds of allowable activity. Thus, research using genetic data would be permitted without consent, eliminating initial hurdles to the commencement of research and further burdens of reconsent when research directions change. To prevent researchers from performing actions viewed as abusive or socially undesirable, liability rules would be put in place. Researchers who violate these rules would be subject to damages, disbarment, and other penalties. However, genetic data would not have to be destroyed or removed from existing data sets, and permissible research using that data could continue unabated. Thus, although deterrents would exist to dissuade individual researchers from engaging in abusive practices, socially beneficial research by others could continue unimpeded.

This liability-based approach is not without precedent. Numerous liability-based regimes already exist to protect individual interests in genetic and other health-related data. Most notable among these is the Genetic Information Nondiscrimination Act of 2008 (GINA), which prohibits discrimination in employment and health insurance on the basis of an individual's genetic profile.[49] This Article argues that a system of well-defined prohibitions on injurious conduct involving personal genetic data would better serve the dual interests of protecting individuals from harm and promoting medical research than the de facto common law property regime that has emerged today. In addition, a generally applicable liability regime would fill the ever-widening gaps that exist in current federal research regulations with respect to research conducted by the

47. *See id.* at 1105–06, 1116, 1119–20.

48. Barbara Evans has written that the current system of federal research regulations embodied in the Common Rule, the HIPAA Privacy Rule, and elsewhere offers a combination of property-like and liability-like features. Evans, *supra* note 11, at 74 & nn.27 & 32, 82–83 (describing the combination of features as "pliability" rules) (first citing Hall & Schulman, *supra* note 13; then citing Abraham Bell & Gideon Parchomovsky, *Pliability Rules*, 101 MICH. L. REV. 1 (2002)). Although I acknowledge the tempering effect that current and proposed exceptions under federal research regulations may have on the control over data exercised by individuals, see *infra* Section I.A, I am not persuaded that these exceptions create a liability- or even pliability-based regime, nor that the perpetuation of the baseline property-like regime established under the guise of informed consent can effectively be mitigated by these limited regulatory safety valves, particularly in view of the common law property principles that have emerged in litigation and which threaten to overcome the balanced approach these regulations seek to achieve.

49. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881, 882–83 (2008) (codified as amended in scattered sections of 29 and 42 U.S.C.).

private sector.[50]

The remainder of this Article proceeds in three principal parts. Part I first reviews the origins and development of the informed consent doctrine under U.S. law then explores how the traditional right to privacy and risks to privacy have become enmeshed in the informed consent doctrine. Part II examines the unintended consequences of applying the informed consent doctrine to genetic data and how the propertization of such data has evolved along the lines of five neoclassical characteristics of property: the right to exclude, the right to destroy, divisibility of rights, dead hand control, and the right to alienate. Part II goes on to discuss the impact that such propertization has had on biomedical research in the context of recent litigation involving infant blood spots and Native American DNA. Part III sets out a proposal to replace informed consent for data usage with a system of liability rules that prohibit particular information practices that are likely to harm individuals.

I. FROM INFORMED CONSENT TO PROPERTIZING CONSENT

The doctrine of informed consent applies to all medical procedures performed in the United States today. It provides that a medical practitioner may perform a procedure on an individual only after that individual is informed of the nature and risks of the procedure and voluntarily consents to undergo it.[51] The doctrine is rooted in the fundamental ethical principles of autonomy and respect for persons, which hold that individuals must be given "the opportunity to choose what shall or shall not happen to them."[52] This Part traces the origins of the informed consent doctrine in the United States from early cases involving involuntary medical treatment to the application of the doctrine to medical research. It then examines how informed consent has been applied to restrict the uses of individual health-related data through the application of privacy law.

A. ORIGINS OF THE INFORMED CONSENT DOCTRINE

A little over one hundred years ago, Justice Benjamin Cardozo, writing in *Schloendorff v. Society of New York Hospital*, stated that every adult of sound mind "has a right to determine what shall be done with his own body."[53] *Schloendorff* involved a patient who successfully sued her physician for assault after he removed a tumor from her abdomen despite her express instructions not

50. *See infra* notes 178–82 and accompanying text.

51. *See* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 117–24 (5th ed. 2009). In addition to medical research, the doctrine of informed consent also applies to procedures performed by physicians and other medical practitioners on patients. *Id.*

52. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, at § C.I (1979) [hereinafter BELMONT REPORT]; *see generally* BEAUCHAMP & CHILDRESS, *supra* note 51; JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE (2d ed. 2001).

53. 105 N.E. 92, 93 (N.Y. 1914).

to operate.[54] Some scholars regard the case as the first to recognize a patient's right to consent to an invasive medical procedure.[55] The modern common law doctrine of informed consent, in which the adequacy of information conveyed to a patient is critical, is usually traced to *Salgo v. Leland Stanford Jr. University Board of Trustees* in 1957.[56] In *Salgo*, the court held that "[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[57] Both *Schloendorff* and *Salgo* concerned the adequacy of a patient's consent to invasive medical *treatment*.

The requirement to obtain informed consent for medical *research* arose in the wake of the Nuremberg "Doctors Trial," in which the inhumane experiments performed by Nazi medical researchers received global attention.[58] The resulting Nuremberg Code (1947–1949)[59] was the first international codification of measures researchers must observe when conducting experiments on human subjects.[60] These measures included obtaining the research subject's voluntary consent, avoiding unnecessary physical and mental suffering, minimizing the risk to the subject, providing adequate facilities, and the like.[61]

Despite nearly universal condemnation of the atrocities revealed at Nuremberg, most medical researchers did not view the Nuremberg Code as applicable to their own practices.[62] Thus, the use of informed consent in research settings was not widespread during the postwar years. Then, beginning in the early 1960s, disturbing cases of civilian research abuse began to emerge in the United States and other countries. These included the infamous Tuskegee Syphilis Study (1932–1972), in which the U.S. Public Health Service observed the progression of syphilis in approximately 400 African-American men without offering them widely available treatments,[63] and the Cincinnati Radiation Experiments (1960–1972), in which university researchers exposed eighty-eight unwitting (predominantly African-American) cancer patients to lethal doses of radiation to study the potential health impacts of a nuclear attack.[64]

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54. According to the plaintiff, the operation caused her left arm to become infected and gangrenous, resulting in the amputation of some of her fingers and other complications. *Id.*

55. *See* Valerie Gutmann Koch, *A Private Right of Action for Informed Consent in Research*, 45 SETON HALL L. REV. 173, 178–79 (2015).

56. 317 P.2d 170 (Cal. Dist. Ct. App. 1957)*; see* Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor is Right" to "Patient has Rights,"* 50 SYRACUSE L. REV. 1243, 1246–47 (2000).

57. *Salgo*, 317 P.2d at 181.

58. *See, e.g.*, BERG ET AL., *supra* note 52, at 250–51.

59. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–82 (1949) [hereinafter NUREMBERG CODE].

60. A few prewar ethical codes in countries including Prussia, Germany, and the United States existed prior to the Nuremberg Code. *See* BERG ET AL., *supra* note 52, at 249–50.

61. NUREMBERG CODE, *supra* note 59, at 181–82.

62. *See* BERG ET AL., *supra* note 52, at 252.

63. *See* TUSKEGEE SYPHILIS STUDY LEGACY COMM., FINAL REPORT OF THE SYPHILIS STUDY LEGACY COMMITTEE—MAY 20, 1996 (1996).

64. *See In re* Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio 1995).

Not all research abuses during this period involved physically invasive procedures. Some notorious examples of noninvasive, yet ethically questionable, social science research include Stanley Milgram's 1963 psychological study of subjects' willingness to inflict pain on others when ordered to do so,[65] and Laud Humphreys's 1969 sociological exposition of gay sex in public restrooms.[66] It was widely acknolwedged that experiments like these have the potential to cause their subjects personal humiliation, mental anguish, and emotional suffering, notwithstanding a lack of physical harm.[67]

Revelations of these research abuses fueled calls for greater protection of human research subjects across the board. The Nuremberg Code was followed by a more detailed codification developed by the World Medical Association—the Helsinki Declaration (1964)[68]—and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research—the Belmont Report (1979).[69] The Belmont Report, in particular, identified three core ethical values that should guide the conduct of research involving human subjects: respect for persons, beneficence, and justice.[70] A key element of respect for individuals is treating them as autonomous by giving weight to their "considered opinions and choices."[71] In other words, giving individuals the opportunity to choose, with the benefit of adequate information, whether to participate in a particular research study. This element gave rise to the current understanding of informed consent for medical research.

The informed consent requirement and other human research protections based on the Belmont Report were adopted into U.S. law in 1981.[72] These are currently codified as part of the so-called "Common Rule" that applies to all federally funded research on human subjects.[73] In September 2015, the Department of Health and Human Services (DHHS), in conjunction with fifteen other federal departments and agencies, issued a Notice of Proposed Rulemaking

65. STANLEY MILGRAM, OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW (1974); Stanley Milgram, *Behavioral Study of Obedience*, 67 J. ABNORMAL PSYCH. & SOC. PSYCHOL. 371 (1963).

66. LAUD HUMPHREYS, TEAROOM TRADE: IMPERSONAL SEX IN PUBLIC PLACES (1970).

67. *See* MARK ISRAEL & IAIN HAY, RESEARCH ETHICS FOR SOCIAL SCIENTISTS 33–34 (2006).

68. WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (1964).

69. BELMONT REPORT, *supra* note 52.

70. *Id.* at pt. B.

71. *Id.* at sec. B.1. The principle of autonomy as a basis of informed consent has been discussed extensively in the literature. *See, e.g.*, JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984); Koch, *supra* note 55, at 203–06 & nn.144–59 (discussing much of the recent literature); Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 610 (2007); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 924 (1994).

72. General Requirements for Informed Consent, 45 C.F.R. § 46.116 (2005).

73. *See id.* Similar requirements are imposed by the U.S. Food and Drug Administration (FDA) on research relating to pharmaceutical products, 21 C.F.R. § 50.20 (2014), and on healthcare records pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

(NPRM) proposing numerous significant amendments to the Common Rule.[74] Among the proposed changes were several revisions to current informed consent requirements. These include an express recognition that every individual donor of tissue or other biological material to a biobank constitutes a "human subject" that must consent to its future use in research.[75] In addition to information about the relevant study and use of data, researchers under the proposed NPRM rules would also be required to inform individuals whether their samples and data would be used for commercial purposes, whether clinically relevant results will be returned to them and under what circumstances, and whether researchers may seek to recontact the individual to participate in future studies.[76]

In addition to these federal regulatory regimes, the informed consent requirement has become embedded in state law governing medical practice and biomedical research.[77] Though state regulations vary considerably, they tend to follow the broad contours of the Common Rule, requiring voluntary informed consent by subjects of medical research.[78] However, state law privacy, tort, and property claims have the potential to upset the balance between the protection of human subjects and the conduct of medical research that state and federal research regulations have sought to achieve.

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74. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933 (Sept. 8, 2015). The NPRM was issued four years after an earlier Advance Notice of Proposed Rulemaking (ANPRM), which attracted hundreds of comments from the public. Human Subjects Research Protections, 76 Fed. Reg. 44,512 (July 26, 2011). For a discussion of the potential impact of the NPRM on the Common Rule consent requirements, see Kathy L. Hudson & Francis S. Collins, *Bringing the Common Rule into the 21st Century*, 373 New Engl. J. Med. 2293 (2015). DHHS received 2,186 comments on the NPRM during the public comment period, many of which expressed significant concern with the NPRM's proposals. COUNCIL ON GOVERNMENTAL RELATIONS AND ASS'N OF PUBLIC & LAND-GRANT UNIVS., ANALYSIS OF PUBLIC COMMENTS ON THE COMMON RULE NPRM (2016). In response to the release of the NPRM and the public comments submitted, the National Academies of Sciences, Engineering, and Medicine issued a report highly critical of the proposal that urged that the NPRM be withdrawn:

> The NPRM is marred by omissions, the absence of essential elements, and a lack of clarity. In addition, important questions about the overall impact and long-term costs of the proposed regulatory changes are unresolved. In light of these deficiencies, it would be impractical to use the current NPRM as the basis for achieving a meaningful, consistent, and harmonious revision of the regulations governing human subjects research that is optimally responsive to developments that have occurred since the publication of the Belmont Report.

NAT'L ACADS. SCIS., ENG'G, & MED., OPTIMIZING THE NATION'S INVESTMENT IN ACADEMIC RESEARCH: A NEW REGULATORY FRAMEWORK FOR THE 21ST CENTURY 167 (2016).

75. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 54,047.

76. *Id.* at 54,053; *see infra* Section II.B.3 (addressing additional proposed rule changes introduced by the NPRM).

77. *See, e.g.*, Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1069–70 (S.D. Fla. 2003) ("[I]n certain circumstances [under Florida law] a medical researcher does have a duty of informed consent."); Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 844 (Md. 2001) (holding that researchers had a duty to disclose that children participating in a study would be exposed to lead paint).

78. *See, e.g.*, *Greenberg*, 264 F. Supp. 2d at 1069–70 (discussing legal rules in New York, Pennsylvania, Maryland, and Ohio and declining to extend Florida's informed consent rule to require the disclosure of researcher economic interests to research participants).

B. CONSENT, PRIVACY, AND DATA

Although the informed consent doctrine provides a necessary bulwark against unethical medical and research practices, it has recently expanded to cover activity that was not contemplated by the Belmont Report and other foundational formulations of research ethics. This expansion is most pronounced with respect to the use of data collected from human research subjects. At first blush, it is not obvious why the informed consent doctrine should apply to data at all. Data-based research is not invasive, does not cause physical suffering, imposes no health risks, and in many cases is conducted in a manner of which the individual is wholly unaware. As such, data-based research is materially different than the invasive nonconsensual research condemned at Nuremberg and Tuskegee and even the damaging psychological experimentation carried out by Milgram and others. Nevertheless, two distinct lines of reasoning have converged to impose informed consent requirements on the use of human subject data: privacy and risk.

1. The Right to Privacy

Much of the discussion surrounding the use of medical research data is grounded in notions of individual privacy: medical data is personal and should thus be utilized only with the consent of the individual. The law surrounding data privacy in the United States is a patchwork of common law torts, constitutional protections, and domain-specific regulations. Significantly, however, none of these regimes establishes a property-based approach to the protection of individual information.

a. Common Law Tort. The right to privacy in the United States is usually traced to an influential 1890 law review article by Samuel Warren and Louis Brandeis.[79] In it, the authors condemn the increasing incursions of tabloid photography and reporting into private life, famously predicting that if this trend continued unabated "what is whispered in the closet shall be proclaimed from the house-tops."[80] To stem this tide of public revelation, Warren and Brandeis proposed the legal recognition of an enforceable right "to be let alone," akin to existing actions for assault, nuisance, and defamation.[81] The authors are careful, however, to explain that this right to privacy should not be considered a new form of property, despite the temptation to do so.[82]

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79. Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890); *see also* PROSSER AND KEETON ON THE LAW OF TORTS 849–50 (W. Page Keeton eds., 4th ed. 1984) (tracing origin of "right of privacy" to Warren and Brandeis's 1890 article).

80. Warren & Brandeis, *supra* note 79, at 195.

81. *Id.* at 205.

82. *Id.* ("The principle . . . is in reality not the principle of private property, but that of an inviolate personality."). This distinction was recognized twenty-eight years later in *International News Service v. Associated Press*, in which Brandeis, then an Associate Justice of the Supreme Court, wrote a now-famous dissenting opinion. 248 U.S. 215, 248 (1918).

In 1960, Dean William Prosser revisited Warren and Brandeis's 1890 article and identified four principal areas in which courts have recognized the right to privacy: intrusion into private affairs, public disclosure of private facts, depiction in a false light, and appropriation of name or likeness.[83] These four variants of the common law right to privacy are still recognized today.[84] Of the four, the one most relevant to personal health data is the prohibition on public disclosure of private facts. This right, and its general acceptance into the common law, has fueled the development of a vast literature concerning the right to privacy in individual information.[85] Nevertheless, even this right, which is rooted in notions of autonomy, has not been recognized by courts as creating a property interest.[86] That is to say, it does not a priori give an individual the right to prevent a particular disclosure from being made. Rather, it provides an actionable tort that may be brought by the aggrieved victim of a violation of the right to privacy.

b. Constitutional Privacy. In addition to the common law tort, a right to privacy grounded in the Due Process Clause of the Fourteenth Amendment has been recognized by the Supreme Court in a line of prominent cases including *Griswold v. Connecticut* (birth control),[87] *Roe v. Wade* (abortion),[88] *Moore v. City of East Cleveland* (family living arrangements),[89] *Cruzan v. Missouri Department of Health* (termination of life-prolonging medical treatment),[90] and *Lawrence v. Texas* (sodomy).[91] In each of these cases, state statutes and regulations limiting individuals' ability to arrange their affairs and make personal decisions were invalidated as impermissibly infringing the constitutional right to privacy.

In the area of criminal procedure, numerous cases under the Fourth Amendment's protection against unreasonable searches and seizures have established

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83. William L. Prosser, *Privacy*, 48 CALIF. L. REV. 383, 389 (1960).

84. *See, e.g.*, Neil M. Richards & Daniel J. Solove, *Prosser's Privacy Law: A Mixed Legacy*, 98 CALIF. L. REV. 1887 (2010) (exploring the influence of Prosser's work on the development of American privacy law) [hereinafter Richards & Solove, *Prosser*]; Daniel J. Solove, *A Taxonomy of Privacy*, 154 U. PA. L. REV. 477 (2006) [hereinafter Solove, *Taxonomy*].

85. *See supra* notes 12–18. As noted by Prosser, "no other tort has received such an outpouring of comment in advocacy of its bare existence." PROSSER AND KEETON ON THE LAW OF TORTS, *supra* note 79, at 850. For a recent snapshot of the volume of scholarly legal literature relating to data privacy, see SSRN's Information Privacy Law eJournal, which, as of this writing, boasted 3,565 different articles on the topic. *Information Privacy Law eJournal*, SOC. SCI. RESEARCH NETWORK, http://papers.ssrn.com/sol3/JELJOUR_Results.cfm?form_name=journalBrowse&journal_id=1125502 [https://perma.cc/W4EF-XQEV].

86. *See, e.g.*, Motschenbacher v. R. J. Reynolds Tobacco Co., 498 F.2d 821, 825–26 (9th Cir. 1974); Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 138 (Cal. 1990); Lugosi v. Universal Pictures, 25 Cal. 3d 813, 818–19, 823–26 (Cal. 1979).

87. 381 U.S. 479, 485–86 (1965).

88. 410 U.S. 113, 153–54 (1973).

89. 431 U.S. 494, 498–500 (1977).

90. 497 U.S. 261, 278–79 (1990).

91. 539 U.S. 558, 578–79 (2003).

limits on the government's collection and use of personal data. This line of cases addresses privacy in recorded personal data in a variety of forms: *Smith v. Maryland* (telephone call registers),[92] *United States v. Miller* (bank records),[93] and, most recently, *United States v. Jones* (GPS location-tracking data).[94] In each of these cases, privacy interests of a criminal defendant were balanced against the state interest in obtaining probative evidence of a crime.

c. Statutory Data Privacy. As John Wilbanks has observed, "[m]ost data collected commercially in the United States today lacks direct protection under the law."[95] Against this backdrop of nonprotection, certain categories of personal data have been singled out for statutory and regulatory protection. Chief among these is personally identifiable health information ("protected health information" or "PHI"), which is regulated under the HIPAA Privacy Rule.[96] The HIPAA Privacy Rule establishes detailed regulations regarding the collection, use, storage, and disclosure of PHI by healthcare providers, laboratories, payers, and other "covered entities." It also establishes rules relating to the use of PHI in a range of research settings including clinical trials, epidemiological studies, and health services research.[97] The results of genetic diagnostic tests (for example, identifying disease predisposition, drug interaction, hereditable conditions, and paternity) and other genetic data are often stored in individual health records and thereby constitute PHI.[98]

Outside of the healthcare setting, a host of domain-specific statutory and regulatory regimes exist to protect individual data at both the state and federal levels. For example, the Fair Credit Reporting Act[99] protects consumer credit information held by credit reporting agencies and the Gramm–Leach Bliley Act protects personal financial information held by a variety of financial institutions.[100] In addition to these specific statutory regimes, under its general authority to prevent "unfair or deceptive acts or practices in or affecting commerce,"[101] the U.S. Federal Trade Commission (FTC) has established a set of Fair Information Practice Principles relating to the online collection and use

92. 442 U.S. 735, 745–46 (1979).

93. 425 U.S. 435, 442–43 (1976).

94. 132 S. Ct. 945, 949 (2012).

95. John Wilbanks, *Portable Approaches to Informed Consent and Open Data*, *in* PRIVACY, BIG DATA, AND THE PUBLIC GOOD: FRAMEWORKS FOR ENGAGEMENT 234, 235 (Julia Lane et al. eds., 2014).

96. 45 C.F.R. pts. 160 & 164 (2003). Though the HIPAA Privacy Rule is the most relevant privacy regulation with respect to genetic data, there are numerous other federal and state regulations regarding the privacy of health-related information. *See* INST. OF MED., *supra* note 28, at 88–90.

97. The HIPAA Privacy Rule has been heavily criticized for obstructing research while at the same time offering insufficient protection for personal health information. *See* INST. OF MED., *supra* note 28, at 2 ("[T]he HIPAA Privacy Rule does not protect privacy as well as it should, and . . . as currently implemented, the HIPAA Privacy Rule impedes important health research.").

98. *See* 45 C.F.R. §160.103 (2003) (defining "individually identifiable health information").

99. Fair Credit Reporting Act, 15 U.S.C. §§ 1681–1681x (2012).

100. Financial Modernization Act of 1999 (Gramm–Leach–Bliley Act), 15 U.S.C. §§ 6801–27 (2012).

101. Federal Trade Commission Act, 15 U.S.C. § 45 (2012).

of personal information.[102] One of the principles established by the FTC is "choice," under which online "data collectors must afford consumers an opportunity to consent to secondary uses of their personal information."[103]

As privacy scholars such as Daniel Solove have observed, the current regulation of individual privacy in the United States is an unwieldy patchwork of common law, constitutional law, and federal and state regulation.[104] As such, privacy has become too amorphous and broad a doctrine to provide reasonable rules for the research use of genetic data. The next section describes how the privacy framework conceptualizes risk associated with the use of genetic data and how the overstatement of risk contributes to the propertization of this data under current law.

2. Data Risks

A basic element of the informed consent doctrine is that a research subject must be given "[a] description of any reasonably foreseeable risks or discomforts" arising from proposed research.[105] The need for such a requirement in medical research is obvious. If researchers are testing an experimental new drug, the recipient should be informed that the treatment may induce nausea, cause ulcers, or, in rare instances, trigger heart failure and death. Knowledge of such serious risks such as these is essential to an individual's voluntary decision to undergo an experimental treatment.

The risks associated with data are, of course, different. Whereas physical procedures and interventions may result in pain, suffering, and adverse health consequences, and even nonphysical psychiatric experiments may cause mental distress and trauma, data-based research will seldom do so.[106] Nevertheless the unauthorized disclosure and use of health-related information can result in harm to an individual. For example, information such as mental health diagnosis, infection status, sexual history, paternity, and ancestry can be severely damaging to an individual's reputation, job prospects, insurance coverage, personal relationships, and emotional well-being.[107] As Leslie Francis and John Francis have observed,

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102. FED. TRADE COMM'N, PRIVACY ONLINE: FAIR INFORMATION PRACTICES IN THE ELECTRONIC MARKETPLACE 4 (2000), http://www.ftc.gov/sites/default/files/documents/reports/privacy-online-fair-information-practices-electronic-marketplace-federal-trade-commission-report/privacy2000text.pdf [https://perma.cc/UX8B-CBLT] [hereinafter FTC PRIVACY PRINCIPLES].

103. *Id.* at 15.

104. *Cf.* Solove, *Taxonomy*, *supra* note 84, at 480–83 (noting the doctrinal disarray of current privacy law).

105. General Requirements for Informed Consent, 45 C.F.R. § 46.116(a)(2) (2005).

106. *See* INST. OF MED., *supra* note 28, at 7 ("[I]n information-based research that relies solely on medical records and stored biospecimens, the research participant faces no risk of direct physical harm.").

107. *See, e.g.*, *id.* at 77; Jonathan Zittrain, *What the Publisher Can Teach the Patient: Intellectual Property and Privacy in an Era of Trusted Privication*, 52 STAN. L. REV. 1201, 1227 & n.83 (2000) (listing numerous "scare stories" about the inappropriate use of personal health data).

> The ability to share knowledge of health information may be important to the establishment of intimacy. Health information may reveal aspects of identity such as genetic relationships, ancestry, or disease status. Job loss, denials of insurance coverage, or refusals to provide credit may be the dire economic costs when health information comes to light.[108]

Similar risks have been identified with respect to genetic information.[109] For example, if individual genetic data were publicly known, employers and insurers might discriminate against individuals with genetic profiles correlated with high risks of illnesses that are costly to treat or which may result in significant sick leave.[110] Genetic information could also be used to discriminate on the basis of race or national origin, even when this information is not readily apparent.[111] And genetic information can be used in criminal forensic analysis to identify individuals and family members, potentially in a manner that goes beyond permissible boundaries of criminal procedure.[112] As the number of genetic markers correlated to specific diseases and physiological traits grows, so too does the risk associated with misuse of this information. A number of scholars have further expanded the notion of risk to encompass group, cultural, and dignitary harms that may result from the unauthorized use of genetic information.[113]

Given these perceived risks, the informed consent doctrine as it is currently interpreted requires that researchers wishing to utilize data obtained from an individual must disclose and explain the risks of the proposed research to the individual and obtain his or her voluntary, informed consent to the use of that data, subject to a limited set of exceptions.[114] However, critics argue that these risks, although theoretically possible, are, in actuality, manageable, both with

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108. Leslie P. Francis & John G. Francis, *Informatics and Public-Health Surveillance*, *in* BIOINFORMATICS LAW: LEGAL ISSUES FOR COMPUTATIONAL BIOLOGY IN THE POST-GENOME ERA 191, 193 (Jorge L. Contreras & A. James Cuticchia eds., 2013).

109. C. Heeney et al., *Assessing the Privacy Risks of Data Sharing in Genomics*, 14 PUB. HEALTH GENOMICS 17, 21–22 (2010); J.M. Oliver et al., *Balancing the Risks and Benefits of Genomic Data Sharing: Genome Research Participants' Perspectives*, 15 PUB. HEALTH GENOMICS 106, 109 (2012).

110. In the United States, discrimination by health insurers and employers on the basis of genetic information was made unlawful under GINA. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 2(5), 122 Stat. 881, 882–83 (2008) (codified as amended in scattered sections of 29 and 42 U.S.C.); *see supra* note 49 and accompanying text. However, GINA does not cover other forms of insurance, including life insurance and long-term disability. *See* Genetic Information Nondiscrimination Act of 2008 § 2(5).

111. For example, under the one-drop rule adopted in some U.S. states during the eugenics movement, any "trace whatsoever of any blood other than Caucasian" could classify someone as "colored," even if that person outwardly appeared white. *See, e.g.*, Racial Integrity Act of 1924, S.B. 219, 1924 Gen. Assemb. (Va. 1924).

112. *See* Heeney et al., *supra* note 109, at 21–22.

113. *See, e.g.*, Katherine Drabiak-Syed, *Lessons from* Havasupai Tribe v. Arizona State University Board of Regents*: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice*, 6 J. HEALTH & BIOMEDICAL L. 175 (2010).

114. *See infra* Section II.C (discussing deidentification and other exceptions under existing federal regulations requiring informed consent for data-driven research).

respect to the individual and relative to the benefits that can be achieved through the use of genetic data in research.[115]

II. CONSENT AND THE PROPERTIZATION OF GENETIC DATA

A. BEGINNING TO LOOK A LOT LIKE PROPERTY

This Part explores the ways in which the requirement to seek informed consent for research using genetic data has resulted in the emergence of property-like rights in that data. In particular, it reviews instances in which classical attributes of property (the right to exclude, the right to destroy, dead hand control, indefinite divisibility, and alienability) manifest themselves with respect to genetic data. It then assesses the implications of these property-like rights on the conduct of biomedical research.

1. The Right to Exclude

Sir William Blackstone famously described property as "that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe."[116] Since Blackstone's day, the right to exclude others from one's property and to enjoy its exclusive use has been counted among the most characteristic and fundamental rights of property ownership. The right to exclude has been cited by the Supreme Court as "[t]he hallmark of a protected property interest"[117] and echoed by many commentators.[118] In its purest form, the right to exclude others from one's property may be exercised irrespective of whether the property owner suffers, or is likely to suffer, any cognizable harm from the incursion.[119]

The right to exclude is also a hallmark of intangible property rights. The owner of a copyright, for example, may prevent others from reproducing, distributing, and making derivative works of her copyrighted work.[120] In numer-

115. *See, e.g.*, INST. OF MED., *supra* note 28, at 7 ("[I]n information-based research that relies solely on medical records and stored biospecimens, the research participant faces no risk of direct physical harm."); *id.* at 9 ("If society seeks to derive the benefits of medical research in the form of improved health and health care, information should be shared to achieve that greater good, and governing regulations should support the use of such information, with appropriate oversight.").

116. 2 WILLIAM BLACKSTONE, COMMENTARIES *2.

117. Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666, 673 (1999).

118. *See, e.g.*, Felix S. Cohen, *Dialogue on Private Property*, 9 RUTGERS L. REV. 357, 374 (1954) (acknowledging a property owner's nearly absolute right to prevent others from entering his property without permission); Thomas W. Merrill, *Property and the Right to Exclude*, 77 NEB. L. REV. 730, 730 (1998); Lior Jacob Strahilevitz, *Information Asymmetries and the Rights to Exclude*, 104 MICH. L. REV. 1835, 1836 (2006).

119. *See* RESTATEMENT (SECOND) OF TORTS § 158 (AM. LAW INST. 1965) (indicating that intentional trespass is a strict liability tort as to which liability will adhere irrespective of whether any harm is caused); Jacque v. Steenberg Homes, Inc., 563 N.W.2d 154, 160 (Wis. 1997) (permitting a property owner to prevent passage over his property for no apparent cause).

120. 17 U.S.C. § 106 (2012).

ous cases seeking the recognition of property-like rights in data, would-be data owners have also sought to prevent others from using or otherwise exploiting data they have collected or generated. But as noted in the Introduction, these data-related cases have been uniformly unsuccessful in U.S. courts.[121] Likewise, legislation debated in Congress during the 1990s would have created property-like rights for data and databases, including the right of data "owners" to prevent usage and other exploitation of their data.[122] But, as noted above, these and similar legislative efforts to propertize data were ultimately unsuccessful.[123]

Despite their failure in the courts and the legislature to extend express property-like protection to data, proponents have succeeded in applying the right to exclude to genetic data through the mechanism of informed consent. For example, in 2009, the Texas Department of Health agreed to destroy a research biobank containing approximately 5.3 million infant blood samples to settle a lawsuit brought by Andrea Beleno and three other Texas parents.[124] The samples were collected over an eight-year period as part of a state program to screen newborns for genetic disorders and birth defects.[125] Such screening programs have historically helped improve infant health and diagnosis, aided in the assessment of environmental exposures, and advanced research on rare diseases.[126]

The plaintiffs' objections arose when they discovered that the state continued to store and use their children's blood samples to conduct research after the initial screening was completed.[127] They argued that the state's failure to obtain their consent to this ongoing research violated their right to privacy under the Fourteenth Amendment, among other things.[128] In settling the litigation, the

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121. *See supra* notes 6–9 and accompanying text.

122. Reichman & Uhlir, *supra* note 10, at 388–95.

123. *See supra* note 10 and accompanying text.

124. Adam Doerr, *Newborn Blood Spot Litigation: 70 Days to Destroy 5+ Million Samples*, GENOMICS L. REP. (Feb. 2, 2010), http://www.genomicslawreport.com/index.php/2010/02/02/newborn-blood-spot-litigation-70-days-to-destroy-5-million-samples/ [https://perma.cc/5KQ8-KT64]; Peggy Fikac, *State to Destroy Newborns' Blood Samples*, HOUS. CHRON. (Dec. 22, 2009), http://www.chron.com/news/houston-texas/article/State-to-destroy-newborns-blood-samples-1599212.php [https://perma.cc/Y2YW-DHBF].

125. *See* Beleno v. Lakey, Order, No. SA-09-CA-188-FB, at 3 (W.D. Tex. Sept. 17, 2009) (describing collection of infant blood samples from 2002 through 2009 when suit was initiated). For an overview of the history of newborn screening programs, see Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 MINN. J.L. SCI. & TECH. 729, 734–37 (2014). In Texas, participation in the screening program was required by law, with a right to opt-out for religious reasons only. *See id.* at 784.

126. *See* Michelle J. Bayefsky et al., *Parental Consent for the Use of Residual Newborn Screening Bloodspots: Respecting Individual Liberty vs Ensuring Public Health*, J. AM. MED. ASS'N, June 8, 2015, at E1, E2.

127. *See* Fikac, *supra* note 123; *see generally* Suter, *supra* note 124, at 754–57 (describing additional research uses of newborn blood spots).

128. *Beleno*, Order, No. SA-09-CA-188-FB at 2. Because the Texas research in question was not carried out under federal grants, the Common Rule did not apply. *See infra* notes 177–81 and accompanying text (relating to spheres of research not covered by the Common Rule).

state agreed to destroy its entire repository of infant blood spots, eliminating any possibility of their use in future research and thereby depriving society of an invaluable and irreplaceable public health resource. Similar lawsuits have occurred in other states[129] and led to the enactment in 2014 of federal legislation requiring explicit parental consent for all research on newborn blood spots.[130]

Another recent example illustrating the exercise of the right to exclude arose in a different context. In 1989, members of the Havasupai Indian Tribe approached researchers at Arizona State University (ASU) "to look into a perceived 'epidemic' of diabetes among tribal members."[131] The researchers collected approximately 200 blood samples from members of the tribe using an informed consent document that purported to authorize research concerning "the causes of behavioral/medical disorders."[132] By 1991, ASU researchers concluded that there was not a genetic link to the high incidence of diabetes within the tribe.[133] Nevertheless, researchers continued to utilize the DNA supplied by the tribe for research into other areas including schizophrenia and ancient human migratory patterns.[134] A tribe member learned of these additional uses in 2003 during a public doctoral dissertation.[135]

Despite the customary and broad language of the original informed consent document, the tribe alleged that its members were led to believe that their DNA samples would be used exclusively for diabetes research and that the additional research was unauthorized.[136] The unauthorized research, tribe members contended, could have led to stigmatizing revelations about individual tribe members or families, particularly given the small size and isolation of the tribe. After settlement discussions failed, the tribe filed suit against ASU and individual researchers in 2004 claiming $50 million in damages.[137] ASU settled the suit in

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129. *See, e.g.*, Bearder v. State, 806 N.W.2d 766, 776 (Minn. 2011) (holding that the use of newborn blood spots for research purposes without consent violated state law). *See generally* Suter, *supra* note 124, at 757–59 (discussing state cases challenging infant blood spot collection and storage).

130. Newborn Screening Saves Lives Reauthorization Act of 2014, Pub. L. No. 113-240, 128 Stat. 2851 (2014) (codified as amended at 42 U.S.C. § 300b).

131. Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063, 1066 (Ariz. Ct. App. 2008). A detailed account of the background and facts of the dispute can be found in Wolf, *supra* note 20, at 118–25.

132. *See* Michelle M. Mello & Leslie E. Wolf, *The Havasupai Indian Tribe Case—Lessons for Research Involving Stored Biologic Samples*, 363 NEW ENGL. J. MED. 204, 204 (2010).

133. *Havasupai*, 204 P.3d at 1067.

134. *Id.*

135. *See* Wolf, *supra* note 20, at 120.

136. *See* Couzin-Frankel, *supra* note 20, at 558 ("The outcome suggests that consent forms alone may not be enough to ensure that subjects understand how their samples may be used or to protect researchers."); Sandra Soo-Jin Lee et al., *The Illusive Gold Standard in Genetic Ancestry Testing*, 325 SCIENCE 38, 38 (2009) (noting of the Havasupai case that "research can be compliant with existing human subjects protections yet fail to recognize long-standing differences in access to institutional and legal power, as well as questions about who holds authority to determine future uses of samples").

137. *Havasupai*, 204 P.3d at 1069–70 (indicating that the tribe's complaint alleged that ASU and individual researchers committed "breach of fiduciary duty, fraud, negligence and trespass"). Although the basis for the tribe's $50 million damages claim was not specified in the complaint, it is possible that

2010 by paying $700,000 to forty-one tribe members and agreeing to return all remaining DNA samples to the tribe.[138] Though, to the author's knowledge, this is the largest settlement that has been paid in a case involving the unauthorized use of a tribal group's data, several other documented cases exist in which research has been curtailed or discontinued after complaints were lodged by indigenous peoples.[139]

These two examples illustrate that research participants have increasingly obtained broad power to prevent "their" data from being used for unauthorized purposes, even when the use of that data poses no physical or psychological threat to them. These cases suggest that earlier precedents such as *Moore v. Regents of the University of California*[140] and *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,[141] which rejected property-like ownership of individual data, are being eroded, if not superseded, by more expansive interpretations of informed consent that imbue data with property-like characteristics. That is, if an individual says not to conduct a particular form of research, or any research at all, using his or her genetic data, then that research should not be conducted.[142] This broad power is, in all but name, a "right to exclude" that constitutes one of the fundamental characteristics of property ownership.

2. The Right to Destroy

Rooted in the ancient Roman principle of *jus abutendi,* another fundamental common law right of property owners is the right to destroy their own property if and when they so desire.[143] On one hand, the right to destroy is anodyne: one must have the ability to discard worn out clothing, broken appliances, and used food packaging in the normal course of life. On the other hand, the right to destroy has been controversial in cases involving unique works of art, historical artifacts, and architecturally significant buildings.[144] Nevertheless, it is widely acknowledged that a property owner may do as she pleases with her property,

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the tribe feared that its federal tribal status, and corresponding benefits, could be challenged based on the results of ASU's human migratory research. The author thanks Leslie Wolf for this insight.

138. *See* Couzin-Frankel, *supra* note 20, at 558; Mello & Wolf, *supra* note 132, at 204.

139. S*ee, e.g.*, Jennifer Couzin-Frankel, *Researchers to Return Blood Samples to the Yanomamö*, 328 SCIENCE 1218 (2010).

140. 793 P.2d 479, 488–93 (Cal. 1990).

141. 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003).

142. *See* Wolf, *supra* note 20, at 142 (arguing that the right to withdraw from a research study necessarily entails the right to prevent further use of genetic material and data).

143. *See* Roscoe Pound, *The Law of Property and Recent Juristic Thought*, 25 A.B.A. J. 993, 997 (1939); Lior Jacob Strahilevitz, *The Right to Destroy*, 114 YALE L.J. 781, 787 (2005).

144. *See* Strahilevitz, *supra* note 143, at 784–85 (discussing critiques by Joseph Sax and Edward McCaffery). Recent calls for international limitations on the right to destroy priceless cultural artifacts have been made in the wake of the Islamic State's destruction of the ruins of the ancient city of Nimrud and many of its artifacts. *See* Graham Bowley & Robert Mackey, *Destruction of Antiquities by ISIS Militants Is Denounced*, N.Y. TIMES (Feb. 27, 2015), http://www.nytimes.com/2015/02/28/world/middleeast/destruction-of-antiquities-by-militants-is-denounced.html?_r=0 [https://perma.cc/C9DZ-MZXJ].

including destroying it, subject only to public safety and similar considerations.[145]

In one sense, data *qua* data cannot be destroyed. A fact, once known to the public, cannot become unknown. However, artifacts containing copies of data, including books, records, and computer storage devices, are routinely destroyed. When data is voluminous and complex, involving more than a few simple facts that can be retained in the human memory, the destruction of the only copies of that data is tantamount to the destruction of the data itself.

For example, the destruction of 5.3 million infant blood samples following settlement of the *Beleno* case resulted in the loss of all diagnostic, epidemiologic, and environmental data contained in those samples. Perhaps the most troubling aspect of that case is the lead plaintiff's admission that she would have permitted research to be conducted on her own children's blood spots had the hospital asked for her permission.[146] However, because researchers failed to seek this consent, she and three other parents eventually forced the state to destroy this irreplaceable public data resource. How was this possible? Because a property owner has a nearly absolute right to order the destruction of her own property, even if she chooses to do so out of anger, annoyance, mistrust, or pique.

3. Divisibility of Rights

Property rights are, by their nature, divisible and separable.[147] Ownership rights in property are often described as a bundle of rights or, metaphorically, a bundle of sticks, in which each "stick" represents a separate legal entitlement with respect to the property.[148] There are, of course, many sticks in this

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145. *See, e.g.*, Eyerman v. Mercantile Tr. Co., 524 S.W.2d 210, 215 (Mo. Ct. App. 1975) ("One is generally restrained from wasteful expenditure or destructive inclinations by the natural desire to enjoy his property or to accumulate it during his lifetime."); RESTATEMENT (SECOND) OF TRUSTS § 124 cmt. g (AM. LAW INST. 1959) ("Although a person may deal capriciously with his own property, his self-interest ordinarily will restrain him from so doing.").

146. Amy Harmon, *Where'd You Go with My DNA?*, N.Y. TIMES (Apr. 24, 2010), http://www.nytimes.com/2010/04/25/weekinreview/25harmon.html [https://perma.cc/9KW6-58RK] ("The irony is if you had asked me, I probably would have consented . . . I would love for there to be a cure for breast cancer, which runs in my family. I would love for there to be a cure for diabetes. The way the state went about it just made me distrustful." (quoting Andrea Beleno, lead plaintiff in *Beleno v. Lakey*)).

147. *See* Henry E. Smith, *Property as Platform: Coordinating Standards for Technological Innovation*, 9 J. COMPETITION L. & ECON. 1057, 1061 (2013) ("Much of what property does, in terms of setting up things and defining rights over them, involves fragmentation and separation . . . . [S]eparation is the key to entity property . . . .").

148. *See, e.g.*, Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979) (referring to the right to exclude as "one of the most essential sticks in the bundle of rights that are commonly characterized as property"); Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 509 (Cal. 1990) (Mosk, J., dissenting) ("[T]he concept of property is often said to refer to a 'bundle of rights' that may be exercised with respect to [an] object—principally the rights to possess the property, to use the property, to exclude others from the property, and to dispose of the property by sale or by gift."); JOHN G. SPRANKLING & RAYMOND R. COLETTA, PROPERTY: A CONTEMPORARY APPROACH 25 (2d ed. 2012) ("[P]roperty is often described as a *bundle of rights* or, more informally, a *bundle of sticks*."). *But see* J.E. Penner, *The "Bundle of Rights" Picture of Property*, 43 UCLA L. REV. 711 (1996) (critiquing the bundle of rights metaphor).

metaphorical bundle. Rights in intellectual property are often subdivided extensively for separate licensing. For example, a single trademark such as the Nike "swoosh" may be licensed to different entities in different geographical regions for different product categories (for example, apparel, footwear, toys, books, jewelry, sports equipment, beverages, snack foods, home furnishings, and computer games). Likewise, a copyrighted work such as a book may be licensed separately for hardcover, mass market paperback, e-book, audiobook, film, television, live theater, soundtrack, podcast, serials, abridgement, and translation into a variety of different languages.[149]

The ability of a data subject to subdivide his or her consent to particular research uses is analogous to the divisibility of property rights. For example, the National Center for Biotechnology Information's Database of Genotypes and Phenotypes (dbGaP) links genetic information with phenotypic data such as the subject's age, ethnicity, weight, demographic profile, environmental exposure, disease state, and behavioral factors, as well as study documentation and statistical results.[150] Under the National Institute of Health's (NIH) current and prior policies, the data subject's informed consent must be obtained for all data submitted to dbGaP.[151] This consent, however, may be highly specific and may limit future research to the study of specific diseases, profit versus nonprofit activities, specified time periods, and types of research. In fact, within the same research study, multiple "consent groups" may exist, each with different permitted uses of their data.[152]

The implicit assumption that one's ability to control the future use of data is separable and divisible strongly evokes a property regime. For example, in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, a group of parents who had provided genetic information to a research institution claimed they retained a property interest in that information.[153] Thus, even though they had consented to the use of the information for research purposes, they argued (unsuccessfully) that their consent did not cover commercial uses that flowed

149. *See* 17 U.S.C. § 201(d)(2) (2012) ("Any of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred as provided by clause (1) and owned separately.").

150. *Database of Genotypes and Phenotypes*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., http://www.ncbi.nlm.nih.gov/gap [https://perma.cc/LFU7-HB7M].

151. *See* Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51,345, 51,347 (Aug. 28, 2014); Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS), 72 Fed. Reg. 49,290, 49,292 (Aug. 28, 2007).

152. For example, in the Alzheimer's Disease Sequencing Project (ADSP) hosted on dbGaP, six different consent groups exist with restrictions including use only for Alzheimer's Disease research, for research on any neurodegenerative diseases, for any research conducted by nonprofit entities, for health/medical/biomedical purposes, and for purposes excluding the study of population origins or ancestry. *Alzheimer's Disease Sequencing Project*, NAT'L INST. ON AGING GENETICS OF ALZHEIMER'S DISEASE DATA STORAGE SITE, https://www.niagads.org/adsp/content/home [https://perma.cc/FTK8-GFAY].

153. 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003).

from discoveries made by the institution.[154] This type of severability of interests was also argued, with greater success, by the Havasupai Tribe. In the *Havasupai* case, the tribe argued that its members' consent to diabetes research did not extend to schizophrenia or human migration research, notwithstanding the breadth of the written consent document.[155]

4. The Dead Hand

Since the late Middle Ages, property owners have been empowered to exert posthumous control over their property through wills, trusts, and other testamentary devices. This phenomenon is loosely referred to as the power of the "dead hand."[156] The infamous (to law students) Rule Against Perpetuities and other legal mechanisms were devised beginning in the seventeenth century to limit the power of a property owner to control the destiny of his property after death.[157] Today, scholars and courts differ as to the amount of deference that should be given to the wishes of deceased owners regarding the fate of their properties.[158] Yet, most agree that, at least for some period of time, a property owner may exert *some* degree of posthumous control over the property that he or she owned while alive.

Surprisingly, a similar body of authority has arisen in the area of data-based research. Donors of tissue, DNA, and genetic data may have the right, through the exercise of informed consent, to control and limit the use of these resources after death.[159] This right does not arise, of course, through the typical justifications for informed consent, as a deceased individual is no longer vulnerable to harm.[160] Rather, it emerges through consideration of potential harms to the

154. *Id.* ("Plaintiffs argue that giving permission for one purpose (gene discovery) does not mean they agreed to other uses (gene patenting and commercialization).").

155. *See supra* notes 130–38 and accompanying text. The case was settled before this issue was adjudicated. *See* Couzin-Frankel, *supra* note 20, at 558.

156. *See generally* Gregory S. Alexander, *The Dead Hand and the Law of Trusts in the Nineteenth Century*, 37 STAN. L. REV. 1189 (1985); Adam J. Hirsch & William K.S. Wang, *A Qualitative Theory of the Dead Hand*, 68 IND. L.J. 1 (1992).

157. Duke of Norfolk's Case (1681) 22 Eng. Rep. 931 (Ch).

158. *See* Eyerman v. Mercantile Trust Co, 524 S.W.2d 210 (Mo. Ct. App. 1975) ("To allow an executor to exercise such power [to demolish an expensive home] stemming from apparent whim and caprice of the testatrix contravenes public policy"); Hirsch & Wang, *supra* note 155, at 3–4 (cataloging competing views on the question, from those advocating for perpetual control by the dead hand, to those advocating the termination of control at death).

159. The Common Rule currently applies only to living subjects. 45 C.F.R. § 46.102(f) (2015). However, state informed consent law and institutional ethical guidelines relating to informed consent impose requirements relating to deceased individuals. *See* NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 29 (1999).

160. In this respect the considerations underlying posthumous consent to the use of data differ from those underlying the need for posthumous consent to organ donation, in which the illusion of lingering life and other factors increase the need for obtaining an individual's consent to organ donation. *See* D. GARETH JONES & MAJA I. WHITAKER, SPEAKING FOR THE DEAD: THE HUMAN BODY IN BIOLOGY AND MEDICINE 111–14 (2d ed. 2009).

deceased individual's *living* relatives.[161] Thus, due to the inherent similarities between the genetic makeup of blood relations, the revelation of stigmatizing or other damaging genetic information about a decedent has been deemed to have the potential to stigmatize or damage his or her living relatives. As a result, the National Bioethics Advisory Commission opined in 1999 that if an individual restricts the use of his or her genetic material while alive, those restrictions should continue to apply after death.[162]

Though the consent requirements of the Common Rule[163] and HIPAA Privacy Rule[164] apply only to living individuals, some institutions are reported to interpret the rules more conservatively and seek consent from a decedent's next of kin before using his or her PHI for research purposes.[165]

Other federal regulations go beyond the Common Rule and HIPAA Privacy Rule in this regard. For example, NIH's 2014 Genomic Data Sharing (GDS) policy has further validated the power of the dead hand with respect to genetic information. Under the GDS policy, individual consent is required in connection with research conducted on any human genetic material obtained using NIH funding, whether or not the data is anonymized, and whether the donor is living or deceased.[166] Thus, for example, if an individual originally consented to the use of her DNA in a study of breast cancer, but after the individual's death researchers determined that she met the criteria for inclusion in a new study of heart disease, it would be impossible for her consent to be obtained, and it is not even clear that consent by her next of kin would suffice.

The need to continue to honor the consent wishes of deceased DNA subjects under the GDS policy gives new power to the dead hand and imposes additional burdens on the conduct of research, particularly with respect to older repositories of data and DNA as to which reconsent of deceased individuals is not possible.

5. Alienability

Another fundamental right of property owners is the right to alienate (that is, transfer and sell) their property.[167] The right of alienation has been viewed as one of the most inviolate rights held by a property owner, and courts have gone

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161. *See* Evan G. DeRenzo, Leslie G. Biesecker & Noah Meltzer, *Genetics and the Dead: Implications for Genetics Research with Samples from Deceased Persons*, 69 AM. J. MED. GENETICS 332, 332 (1997); Béatrice Godard et al., *Data Storage and DNA Banking for Biomedical Research: Informed Consent, Confidentiality, Quality Issues, Ownership, Return of Benefits. A Professional Perspective*, 11 EUR. J. HUM. GENETICS S88, S94 (2003).

162. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 159, at 29.

163. General Requirements for Informed Consent, 45 C.F.R. § 46.116 (2005).

164. 45 C.F.R. § 164.512(i)(1)(iii) (2006).

165. INST. OF MED., *supra* note 28, at 172.

166. Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51,345, 51,347 (Aug. 28, 2014); *see also* Jorge L. Contreras, *NIH's Genomic Data Sharing Policy: Timing and Tradeoffs*, 31 TRENDS IN GENETICS 55, 55 (2015).

167. *See* JESSE DUKEMINIER ET AL., PROPERTY 232–33 (8th ed. 2014).

to great lengths to avoid even consensual restrictions on an owner's right to dispose of his or her property.[168]

The right to alienate necessarily implies a right to sell and profit from one's property. In several notable cases, individuals have sought to exercise a right to alienate their genetic material, sometimes for profit. For example, in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the plaintiffs sought a share of the profits that Miami Children's Hospital made from discoveries based on their genetic data.[169] In *Washington University v. Catalona,* individual tissue donors, at the request of their physician, instructed Washington University to transfer their tissue and associated data to the physician's new institution.[170]

These attempts to assert property-like authority over the alienation of genetic data were ultimately unsuccessful. Nevertheless, several scholars have proposed that property rights be recognized in individual health information specifically to encourage the development of markets in such data.[171] Thus, although a right of free alienation of genetic data, including the ability to profit from its sale, has not yet been recognized by the courts, there is some momentum toward the incorporation of this aspect of property law into the bundle of rights associated with genetic data.

B. WHERE CONSENT FALLS SHORT

Section II.A. above illustrates ways in which the informed consent doctrine, as it is currently implemented, has imbued personal genetic data with the character of private property in a manner that has the potential to impede scientific research. Defenders of the informed consent approach, however, point out that potential research participants are often willing to consent to such research. This Section explains why relying on the voluntary consent of individuals to research using genetic and other data does not overcome the property-based issues raised above.

1. General Critiques of Informed Consent

The doctrine of informed consent has come under attack in recent years from a variety of quarters. Barbara Koenig has provocatively asserted that, "the focus on consent in contemporary biomedical research has become the modern equiva-

168. *See, e.g.*, White v. Brown, 559 S.W.2d 938, 941 (Tenn. 1977) ("[The testatrix's] attempted restraint on alienation must be declared void as inconsistent with the incidents and nature of the estate devised and contrary to public policy."); Mountain Brow Lodge No. 82 v. Toscano, 64 Cal. Rptr. 816, 817 (Cal. Ct. App. 1967) ("Conditions restraining alienation, when repugnant to the interest created, are void." (quoting Cal. Civ. Code § 711)).

169. 264 F. Supp. 2d 1064, 1075–76 (S.D. Fla. 2003).

170. 490 F.3d 667, 672 (8th Cir. 2007).

171. *See supra* note 13 and accompanying text (discussing views of Allen, Hall, Partlett, Rothstein, and Schulman). By the same token, others have warned against the potential commoditization of such data on moral and ethical grounds. *See supra* notes 16–17 and accompanying text (discussing views of Baron, Radin, and Suter).

lent of a fetish."[172] Like clickwrap agreements for computer software, much informed consent documentation has become so lengthy, complex, and turgid that all but the most sophisticated readers have difficulty understanding it.[173]

Other research has shown that informed consent outcomes can be manipulated through the manner in which questions are posed and the wording used in consent forms.[174] These findings suggest that "informed" consent is not really informed at all, nor is it achieving its intended purpose of empowering individuals to make autonomous decisions about their health.[175] Additional studies and surveys also find that the enhanced consent and other requirements imposed by the HIPAA Privacy Rule, among others, significantly increase both the difficulty of recruiting participants to medical studies[176] and the cost of conducting medical research.[177]

Another group of critics observes that informed consent requirements exist only within a limited set of research environments. That is, the requirement to obtain an individual's consent to research is imposed by the Common Rule[178] (applicable to federally funded research), the HIPAA Privacy Rule[179] (applicable to healthcare records), and the FDA's version of the Common Rule[180] (applicable to drug development research). However, none of these legal regimes expressly apply to research funded by state or local governments or philanthropic organizations or to increasingly prevalent private sector data-driven research projects conducted by organizations such as Facebook, Twitter, Google, and OkCupid.[181] As John Wilbanks observes, "[s]tart-up companies, telecommunications providers, and others are almost entirely unaffected [by data privacy regulations] as they gather metadata and actual data from which health, and identity, can be inferred."[182] These organizations operate outside the

172. Barbara A. Koenig, *Have We Asked Too Much of Consent?*, 44 HASTINGS CENT. REP. 33, 33 (2014).

173. Of clickwrap agreements, Chief Justice John Roberts of the Supreme Court recently admitted that even he does not read the fine print of online agreements or medications. Debra Cassens Weiss, *Chief Justice Roberts Admits He Doesn't Read the Computer Fine Print*, A.B.A. J. (Oct. 20, 2010, 12:17 PM), www.abajournal.com/news/chief_justice_roberts_admits_he_doesnt_read_the_computer_fine_print [https://perma.cc/5WW4-K9YV].

174. *See* Howard Brody, *Transparency: Informed Consent in Primary Care*, 19 HASTINGS CENT. REP. 5, 5 (1989) ("Physicians may also view informed consent as an empty charade, since they are confident in their abilities to manipulate consent by how they discuss or divulge information.").

175. *See* Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69 (1994); Koenig, *supra* note 171, at 33 ("[M]ounting evidence suggests the distance between the ideal of consent and its actual practice."); Peter H. Schuck, *supra* note 71, at 903–05.

176. INST. OF MED., *supra* note 28, at 218–20 (providing an overview of studies of increased recruitment difficulty arising from privacy procedures).

177. *Id.* at 218–20 (providing an overview of studies of increased cost of research based on privacy procedures).

178. General Requirements for Informed Consent, 45 C.F.R. § 46.116 (2005).

179. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29 and 42 U.S.C.).

180. 21 C.F.R. § 50 (2014).

181. *See, e.g.*, Rothstein, *supra* note 20, at 425–26.

182. Wilbanks, *supra* note 95, at 237.

scope of current informed consent requirements, yet the data-based research they conduct is equally, if not more, likely to result in the privacy harms that the informed consent regulatory structure is intended to address.

These broad critiques of the informed consent doctrine apply with equal force to healthcare interventions as well as biomedical research. In the following Sections, I examine several ways in which the doctrine of informed consent is particularly unsuited to the regulation of research using individual genetic data.

2. Limitations of Consent in Data-Driven Research

Proponents of the current informed consent system point out, with some justification, that seeking consent from research participants does not always stymie the conduct of research. Rather, it ensures that individuals permit desired research to be conducted using data obtained from them. Several recent studies have shown that, if asked, many patients are willing to allow research to be conducted using data and samples collected from them.[183]

Nevertheless, the fact that many individuals are willing to grant consent to data-based research does not alleviate all concerns with the need to obtain consent. First, there will always be some members of a population who refuse to consent to the use of their data. The reasons for this refusal can range from concerns over privacy, a general suspicion of the medical establishment, negative past experiences with the same or different investigators, or pure personal preference. Such individuals will simply not participate in the proposed research, and any significant level of nonparticipation invariably introduces consent or selection bias into studies.[184] That is, data and study results become skewed toward those individuals who are most willing to consent to research, whereas individuals who are less willing to consent are underrepresented.[185] Although clear phenotypic distinctions between those who are willing and unwilling to grant consent have not been identified, studies have shown that members of certain minority populations and individuals with lower educational attainment are often hesitant to grant consent to research.[186] For reasons of

183. *See, e.g.*, David Kaufman et al., *Subjects Matter: A Survey of Public Opinions About a Large Genetic Cohort Study*, 10 GENETICS IN MED. 831, 836–37 (2008) (detailing that 90% of U.S. respondents said they would be willing to have samples placed in biobank for research); Evette J. Ludman et al., *Glad You Asked: Participants' Opinions of Re-Consent for dbGap Data Submission*, 5 J. EMPIRICAL RES. ON HUM. RES. ETHICS 9, 14 (2010) (detailing that 86% of respondents gave consent to use of deidentified data for future research use); S.B. Trinidad et al., *Research Practice and Participant Preferences: The Growing Gulf*, 331 SCIENCE 287 (2011).

184. *See* INST. OF MED., *supra* note 28, at 209 ("Selection bias occurs if the individuals who give permission for researchers to access their medical data differ from the group of individuals who are unwilling to give permission for their health information to be used in research.").

185. Evidence of consent selection bias has been documented in numerous studies. *See id.* at 209–14 (providing an overview of studies of consent selection bias).

186. *See, e.g.*, Katherine M. Brown et al., *Differences in Preferences for Models of Consent for Biobanks Between Black and White Women*, 7 J. COMMUNITY GENETICS 41 (2015); Sharon Hensley Alford et al., *Participation in Genetic Testing Research Varies by Social Group*, 14 PUB. HEALTH

social justice and public health, it is undesirable to exclude these segments of the population from health-based research.

Finally, under current informed consent guidelines and practices, it is often the case that consent is obtained for the use of genetic data only in specific studies.[187] Thus, as discussed above in terms of the "divisibility" of rights,[188] even a willing participant may sometimes need to be located and asked for consent again (reconsent) when a different use will be made of his or her data. Although reconsent is possible in some cases, it can introduce significant additional expense, delay, and uncertainty to studies, particularly if the original consent was obtained years earlier.

3. Broadening Consent

In part to address the reconsent issue discussed above, researchers have increasingly sought to obtain broad or generalized consent (for example, to "conduct all forms of biomedical research") from individual research participants at the outset of a research program to avoid having to go back to individuals to seek consent for follow-on studies.[189] Attempts to obtain broad consent are expressly authorized by federal research regulations. For example, the 2014 NIH Genomic Data Sharing Policy requires that all NIH-funded investigators obtain broad consent from individuals contributing DNA data to a genomic study to share that data on an unrestricted basis with the public for any number of unspecified future uses.[190] And in its 2015 NPRM, the federal government proposed amendments to the Common Rule that would authorize one-time general consents for much data-based research.[191]

Although obtaining broad consent may allow researchers to overcome issues with reconsent, it is not itself a solution to the propertization issues described in this Article. First, as one group of researchers observes, "[a] broad consent form . . . may provide legal cover to the researcher . . . but such protections may not promote trust between researchers and participants."[192] This lack of trust can lead to significant backlash from research participants and, as it did in the case of the Havasupai, to litigation, the assertion of rights in genetic material, and the destruction of valuable research resources. But even without litigation,

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GENOMICS 85 (2011); Jasmine A. McDonald et al., *Understanding Participation by African Americans in Cancer Genetics Research*, 104 J. NAT'L MED. ASS'N 324 (2012).

187. For a discussion on the use of broad or so-called "blanket" consent covering multiple future uses, see *infra* notes 188–90 and accompanying text.

188. *See supra* Section II.A.3.

189. *See* Mello & Wolf, *supra* note 132, at 205 (describing different levels of informed consent for stored specimens, ranging from specific to tiered to general to presumed (opt-out) consent).

190. Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51,345 (Aug. 28, 2014). Likewise, many biobanks now request broad consent to future research from tissue donors. *See* Mello & Wolf, *supra* note 132, at 205.

191. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 54,049 (proposed Sept. 8, 2015).

192. S.B. Trinidad et al., *supra* note 183, at 288.

reduced trust may lead individuals who are otherwise suspicious of research to deny broad consent for unspecified future research.[193] If fewer individuals elect to participate in studies that seek broad consent, the problems of nonparticipation and consent bias discussed in Section II.B.2 above may be exacerbated.

Second, some critics have observed that broad informed consent may not be informed at all.[194] As discussed in Section II.B.1 above, standardized consent forms that resemble clickwrap software agreements, permitting every possible future research use and eliminating the individual's ability to contest these uses, hardly achieve the ethical purposes that the informed consent requirement was designed to achieve, and are likely vulnerable to attack on both legal and ethical grounds.[195] To underscore the point, it is hardly likely that seeking such broad consent would be tolerated in the realm of invasive medical procedures. What rational person would voluntarily consent to undergo any medical procedure, tissue extraction, or experiment that any researcher anywhere in the world desired to perform in the future? This distinction intuitively reemphasizes the difference between invasive research and research limited to data. Narrow and voluntary informed consent remains necessary and appropriate for invasive medical procedures, but it may have outlived its usefulness in the case of data-based research.

Third, a research institution's institutional review board (IRB) may not always recognize broad consent, even when permitted under federal regulations. Many IRBs, interpreting not only federal regulations but also their own institutional policies and ethical guidelines, require that researchers seek specific consent for additional research, even when broad consent has previously been obtained and research is arguably exempt from the consent requirements of the Common Rule.[196]

Finally, despite its authorization under federal regulations, broad consent may not be particularly effective to stave off competing common law claims. The example of the Havasupai Tribe illustrates this point. Despite the existence of a broad consent to research concerning "the causes of behavioral/medical

193. *See* Mello & Wolf, *supra* note 132, at 206 (indicating that a "sizable minority" of the public "prefers to be asked for specific consent for new uses"); Krishanu Saha & J. Benjamin Hurlbut, *Treat Donors as Partners in Biobank Research*, 478 NATURE 312, 312 (2011) ("[W]e believe that [the ANPRM's blanket consent proposal] will decrease, not increase, public involvement in biobanks . . . .").

194. *See* Mello & Wolf, *supra* note 132, at 205 (describing the view that "such consent is not informed because without knowing the nature of the studies, one cannot evaluate the risks and benefits of participation"); Christian M. Simon et al., *Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models*, 13 GENETICS MED. 821, 822 (2011) ("Some have insisted that broad consent should not even be thought of as 'informed consent . . . .'").

195. *See* Couzin-Frankel, *supra* note 20, at 558 ("[C]onsent forms alone may not be enough to ensure that subjects understand how their samples may be used . . . .").

196. *See* Mello & Wolf, *supra* note 132, at 205. The American Society of Human Genetics has, for the past two decades, maintained a policy against blanket consent when samples may be identifiable in subsequent studies. AM. SOC'Y HUMAN GENETICS, *Statement on Informed Consent for Genetic Research*, 59 AM. J. HUM. GENETICS 471, 473 (1996).

disorders,"[197] the tribe asserted property-like control over its members' DNA samples and genetic data to prevent their use for research unrelated to diabetes.[198]

C. THE LIMITED EFFECTIVENESS OF DEIDENTIFICATION AND OTHER EXCEPTIONS UNDER FEDERAL CONSENT REGULATIONS

Defenders of existing federal regulations for data-based research also point out that under current regulatory regimes, not all research requires individual consent to move forward.[199] In particular, the Common Rule and HIPAA Privacy Rule each provide an exception from the informed consent requirement for data that has been "deidentified" so that it cannot be traced back to the original research participant. Specifically, the Common Rule consent requirement does not apply when research involves only existing data that "is recorded by the investigator in such a manner that subjects *cannot be identified*, directly or through identifiers linked to the subjects."[200] Likewise, the HIPAA Privacy Rule excludes deidentified data from its definition of PHI, thereby opening deidentified data for research use without a requirement to obtain consent.[201]

Although the deidentified data exceptions of the Common Rule and HIPAA Privacy Rule have enabled many data-based research projects to move forward without obtaining informed consent from individuals, these exceptions fall short in three significant respects. First, as noted above,[202] each of these federal regulatory regimes covers only limited domains: the Common Rule applies only to federally funded research, HIPAA applies only to healthcare records, and the FDA's version of the Common Rule applies only to pharmaceutical research. There are significant gaps in this coverage, most notably with respect to increasingly prevalent private sector "big data" research projects.[203]

Second, the rules themselves do not cover all data-based research within their domains. In particular, the deidentified data exception of the Common Rule covers only existing data sets,[204] and does not extend to research in which the collection of data will be necessary. Likewise, the HIPAA Privacy Rule exceptions for deidentified data are highly complex and impose numerous technical

197. *See* Mello & Wolf, *supra* note 132, at 204.

198. *See supra* notes 131–39 and accompanying text.

199. In addition to the exception for deidentified data, discussed here, numerous other exceptions permitting the use of individual medical data for research exist under HIPAA and the Common Rule. *See* Barbara J. Evans, *Ethical and Privacy Issues in Pharmacogenomic Research*, *in* PHARMACOGENOMICS: APPLICATIONS TO PATIENT CARE 313 (Howard L. McLeod et al. eds., 2d ed. 2009).

200. 45 C.F.R. § 46.101(b)(4) (2015) (emphasis added). This exclusion would largely be preserved under the NPRM. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,960 (Sept. 8, 2015).

201. 45 C.F.R. § 164.514(a) (2006) ("Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information."). Subsequent provisions discuss, at length, the means by which individual health information can be deemed to be deidentified.

202. *See supra* Section II.B.1.

203. *Id.*

204. 45 C.F.R. § 46.101(b)(4) (2005).

requirements before data can be considered deidentified.[205]

Perhaps the most critical shortcoming of deidentified data exceptions is the growing realization that true deidentification of genetic data may, in fact, be difficult or impossible to achieve. The first indication that individuals could be "reidentified" from anonymized genetic data surfaced in 2008, when researchers demonstrated that the presence of an identifiable individual's DNA can be statistically inferred from a group of otherwise anonymous samples.[206] These findings prompted NIH temporarily to block public access to its dbGaP database of genomic data until it could revise its access policies and procedures.[207] In 2013, another study demonstrated that the identity of an "anonymous" male DNA donor could be discovered using only a partial sequence from his Y chromosome, his age, and his U.S. state of residence.[208] This mounting evidence has convinced many that "the end of genomic privacy has arrived"[209] and genetic data simply cannot definitively be deidentified.[210]

As a result, the exceptions for conducting research using deidentified data contained in the Common Rule and HIPAA Privacy Rule may largely be moot, at least with regard to genetic data. That is, if as a practical matter it is not possible to deidentify data reliably and completely, then an exception that permits unconsented research using deidentified genetic data offers little. Rather, researchers may have to go back to square one, seeking informed consent from individuals even for studies that had previously been permitted under deidentified data exceptions. This approach is being taken by an increasing number of IRBs, which conservatively require reconsent of participants even when doing so is arguably not required.[211]

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205. *See* 45 C.F.R. § 164.514(b) (2006). The vagaries of the HIPAA Privacy Rule and how it defines adequate deidentification of data are beyond the scope of this article. For a thorough discussion of these issues, see Evans, *supra* note 11, at 82–84.

206. *See* Jennifer Couzin-Frankel, *Trust Me, I'm a Medical Researcher*, 347 SCIENCE 501, 502 (2015) (discussing implications of Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, 4 PLOS GENETICS e1000167, e1000167 (2008)).

207. Elias A. Zerhouni & Elizabeth G. Nabel, *Protecting Aggregate Genomic Data*, 322 SCIENCE 44, 44 (2008). NIH's solution to the potential identifiability of human subjects in dbGaP was to move some genomic data from the "open" to the "closed" sections of the site, thus giving access only to approved investigators rather than the public at large. *See* Wilbanks, *supra* note 95, at 238.

208. John Bohannon, *Genealogy Databases Enable Naming of Anonymous DNA Donors*, 339 SCIENCE 262, 262 (2013).

209. Couzin-Frankel, *supra* note 206, at 502.

210. *See, e.g.*, Sejin Ahn, *Whose Genome Is It Anyway? Re-identification and Privacy Protection in Public and Participatory Genomics*, 52 SAN DIEGO L. REV. 751, 768 (2015). Moreover, some bioethicists view deidentification of data as largely irrelevant to concerns over individual autonomy. *See* Couzin-Frankel, *supra* note 205, at 503 (citing a 2007 study finding that 81% of respondents "were not happy to have researchers parsing even so-called deidentified health data without their consent" and quoting Mark Rothstein, "[l]et's assume that you've de-identified, anonymized, and nobody can figure out who it is—but if people think you've used that information without their permission, they're still going to be very angry").

211. *See* Simon et al., *supra* note 194, at 821 (indicating that even when regulatory exemptions may apply, consent is sought to "satisfy public and other stakeholder expectations").

What's more, complete deidentification of data, or divorcing genetic sequence data from all associated clinical data and phenotypic traits and characteristics, may actually render the data less useful. That is, one of the most significant research benefits to be derived from genetic data is its association with other physiological conditions, whether those associations relate to increased disease risk, susceptibility to conditions such as obesity, or reactions to therapeutics and other substances.[212] Yet the more phenotypic characteristics that are associated with a particular DNA sample, the greater the likelihood the sample can be reidentified.[213] Thus, aggressive deidentification of data for purposes of circumventing informed consent requirements could actually reduce the scientific value of that data.[214]

D. PRECISION MEDICINE AND AN INFORMED CONSENT ANTICOMMONS?

Taken together, the right to exclude, the right to destroy, the continuation of rights after death, the divisibility of rights, and the right to alienate all point to the conclusion that, notwithstanding clear statements of the law to the contrary, individual genetic data is, in practice, treated today as de facto property owned by the individuals from whom it is obtained. Allowing individuals to exert property-like control over their genetic information through the mechanism of informed consent can have significant deleterious effects on research.[215] Moreover, the exceptions and approaches of informed consent that have previously been relied upon are fraying at the edges and are not likely to be adequate in the future.[216]

For example, if an individual who has consented to broad data usage later asserts that her informed consent was not obtained for a particular study, the investigators performing the study could be required to remove her data from the study and return or destroy her genetic material.[217] As a result, the study in question would, at best, be delayed while discussion and analysis of the consent issue was considered. The statistical analysis would need to be repeated to eliminate the effects of any data removed from the study. In some cases, the removal of data might invalidate the statistical bases for the study and require new data collection. At worst, if enough data were removed, the study itself could be invalidated, resulting in both a loss of valuable knowledge, a delay in understanding the relevant biological mechanisms, and a waste of the public funding that was used to conduct the study.

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212. *See* JAMES D. WATSON, DNA: THE SECRET OF LIFE 165–66 (2003).

213. *See* Wilbanks, *supra* note 95, at 236.

214. *See id.* ("[W]e need to know a lot about an individual to properly make use of that individual's data in a scientific research context, but precisely by knowing a lot about the individual, we degrade the ability to guarantee that individual's anonymity.").

215. *See supra* Section II.A.

216. *See supra* Section II.B, II.C.

217. *See* Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063 (Ariz. Ct. App. 2008).

The prospect of postcommencement consent-based demands to remove or redact data from research studies will also require investigators to take additional precautions at the outset. For example, investigators will be required to maintain sufficient individual-level identification of data elements so as to be able to locate and remove the relevant data when required. They will need to retain the ability to redact data on an individual basis and reanalyze remaining data. If they wish to avoid scrapping entire data sets, they will need to be prepared to seek reconsent of potentially large populations of individuals and redact any data that is not properly reconsented. All of these precautions will add time and expense to studies of human genetic data.[218] When considering the massive scale on which projects such as the PMI are intended to operate, such delays and costs could be significant.[219] And the potential cost of removing data from PMI-scale studies after they have commenced, possibly jeopardizing the scientific validity of those studies, could be catastrophic.

Granting property-like rights to individual research participants has the potential to create an anticommons of significant proportions. Whereas Heller and Eisenberg worried that seeking patent license rights from a few dozen or hundred patent holders could seriously hinder biomedical research,[220] the ramifications of obtaining propertized consent for data use from millions of individuals is far more daunting.

In describing the PMI, Francis Collins, Director of the National Institutes of Health, and Harold Varmus, Director of the National Cancer Institute, admitted that "new approaches to participation and consent" would need to be developed.[221] But given cases such as *Beleno* and *Havasupai*, which resulted in the destruction of large and irreplaceable data resources,[222] it appears that the mechanism of informed consent for data-based research may be broken beyond repair. Simply tweaking this doctrine to address the massive data-based research projects of the future will not be enough. Rather, the approach to genetic data usage should be reconsidered in its entirety.

E. THE INTERSECTION OF FEDERAL RESEARCH REGULATIONS AND PROPERTY LAW

The Common Rule, HIPAA Privacy Rule, and other federal research regulations currently permit much data-based research to be conducted without the need for individual informed consent.[223] But although these regulations may authorize such research from a federal administrative standpoint, they have

218. *See* INST. OF MED., *supra* note 28, at 214–18 (providing an overview of studies of increased cost of research based on privacy procedures).

219. *See* Burton, Rockoff & Winslow, *supra* note 34 (discussing scale and scope of proposed PMI).

220. Heller & Eisenberg, *supra* note 29, at 700.

221. Collins & Varmus, *supra* note 33, at 795.

222. *See* Beleno v. Lakey, Order, No. SA-09-CA-188-FB, at 2–6 (W.D. Tex. Sept. 17, 2009); Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063, 1070 (Ariz. Ct. App. 2008).

223. *See supra* Section I.A.

little impact on state common law rights and duties of researchers or research participants.[224]

Thus, even when researchers fully comply with administrative and institutional requirements regarding informed consent, as they arguably did in *Havasupai*, such compliance does not exonerate or insulate them from common law property or tort claims that may be asserted when aggrieved individuals or groups believe their rights have been violated.[225] Likewise, in *Beleno*, Texas hospitals' compliance with relevant state regulations concerning the collection and use of infant blood spots did not deter the suit that resulted in the destruction of the state's entire repository of infant blood spots.[226]

Thus, just as the manufacturer of a microwave oven may be liable for injuries caused by design defects in the product even if it complied with all applicable federal and state safety standards,[227] exemptions from consent requirements under federal research regulations will not necessarily excuse a researcher's failure to obtain an individual's informed consent under state tort law or observe the individual's property-like interests in his or her data. Accordingly, relying on the consent exemptions available under federal research regulations to ensure that important biomedical research can continue in the face of increasing common law property claims is both shortsighted and inadequate.

III. A LIABILITY RULE FRAMEWORK FOR DATA-BASED RESEARCH

As discussed in Parts I and II, the current system of informed consent for research on human genetic data is not well-suited to the type of large-scale research products that may be necessary to advance medicine and human health in the next century. This Part offers an alternative to the consent-based property system for data-based research that is currently in force. The proposed system utilizes a liability-based framework for protecting individual privacy while allowing research to advance.

A. PROPERTY RULES AND LIABILITY RULES FOR DATA RESEARCH

Research on human genetic data should be governed under a liability rule regime. That is, rather than requiring informed consent from contributors of genetic data to a study, data-based research should be broadly permitted without consent.[228] In place of consent, positive regulations should prohibit researchers

224. *See supra* Section I.B.

225. *See Havasupai,* 204 P.3d at 1063.

226. *See* Beleno v. Lakey, Order, No. SA-09-CA-188-FB, at 3 (W.D. Tex. Sept. 17, 2009).

227. It is a relatively settled principle of tort law that compliance with governmental regulations does not provide a tortfeasor with a complete defense (the so-called "regulatory compliance defense"). *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 288C (AM. LAW INST. 1965); Mark A. Geistfeld, *Tort Law in the Age of Statutes*, 99 IOWA L. REV. 957, 991 (2014). Although evidence of compliance with regulations may be presented to a jury, it is not itself exculpatory or a complete defense to claims of injury.

228. From a practical standpoint, this would eliminate the informed consent requirements for data-based research from the Common Rule, the HIPAA Privacy Rule, and related regulations.

from misusing this data in a variety of ways and create a cause of action if these prohibitions are violated.

At first blush, this proposal may seem to disregard widely held ethical principles, because it eliminates the long-standing requirement to obtain informed consent from individuals prior to conducting research on them. But this is not the case. First, the proposal applies only to noninvasive data-based research and would leave the informed consent requirement intact with respect to physical, psychological, and other forms of direct human experimentation, including any nontrivial physical procedures used to collect DNA from individuals.[229] Second, the proposal does not seek to eliminate protection for individuals in the case of research on data. Rather, by adopting a liability regime over a property regime, it would offer uniform protection to all research participants, thus eliminating the current inconsistencies in protection for federally funded and private sector research.[230] Finally, the proposed liability rule approach is merely an extension of existing restrictions on the use of human genetic data. As such, the proposal would replace the current informed consent system for data usage with an enhanced set of usage restrictions.

As originally conceptualized by Calabresi and Melamed, property rules and liability rules trigger action at different points in time, leading to differing cost burdens on transacting parties.[231] That is, a property rule establishes entitlements that can only be infringed with the advance permission of the rights holder.[232] A liability rule, on the other hand, only gives rise to a remedy when someone violates its strictures.[233] Thus, in a property-based system, a landowner would be permitted to prevent others from entering his property, for example, by erecting a fence or relying on legal enforcement (border patrols) to prevent trespassers from entering. In a liability regime, the landowner would not

229. The historical development of the informed consent rule, from the Nuremberg Code to the Belmont Report to the Common Rule, *see supra* Section I.A, supports the notion that the rule was intended first and foremost as a means for protecting individuals from coerced (and inhumane) procedures carried out in the name of research, and less for the protection of privacy inherent in data-based research. *See* INST. OF MED., *supra* note 28, at 250 ("It was primarily considered a protection against physical harm, permitting informed, competent patients to refuse unwanted medical interventions, to choose among medically available alternatives, and to make choices that conflict with the wishes of family members or the recommendations of physicians."); Alan R. Tait, *Priorities for Disclosure of the Elements of Informed Consent for Research: A Comparison Between Parents and Investigators,* 12 PAEDIATRIC ANAESTHESIA 332, 335 (2002) (finding that confidentiality is one of the least important considerations for potential research participants). *But see* Rothstein, *supra* note 20, at 426 ("The regulation of research is intended to protect against both physical and dignitary harms.") Accordingly, this proposal would only impose affirmative consent requirements when sample collection involves a risk of physical or mental duress. Consent would not be required for noninvasive or risk-free sample collection through cheek swabs, residual hair and skin collection, and discarded tissue from otherwise permitted procedures.

230. *See supra* notes 178–82 and accompanying text.

231. *See* Calabresi & Melamed, *supra* note 45, at 1094–98.

232. *See id.* at 1092.

233. *Id.*

have a right to keep others off his land, but if someone did impermissibly enter his property, he could sue to recover damages.

Like other property rule regimes, an informed consent system requires that procedural requirements be satisfied before research can begin. That is, research cannot be conducted using individual genetic data without the individual's informed consent.[234] Under a liability rule system, however, legitimate research using genetic data would be permitted without consent, thereby eliminating initial hurdles to the commencement of research and future burdens of reconsent when research directions change.

But to prevent researchers from performing actions viewed as abusive or otherwise socially undesirable, liability rules would be put in place. Researchers who violate these rules would be subject to liability, including damages and disbarment penalties.[235] However, data would not have to be destroyed or removed from data sets, and permissible research using that data could continue unabated. In the following Sections, I argue that this approach is preferable to the current informed consent regime from an overall social welfare standpoint and would not sacrifice any meaningful protection currently afforded to sources of genetic data. On the contrary, such protection may actually increase if lawmakers wish to enhance existing liability regimes with additional restrictions.

And what of the existing informed consent requirements contained in the Common Rule, HIPAA Privacy Rule, and elsewhere? These rules should be amended to eliminate informed consent requirements for data-based research.[236] More importantly, once federal agencies abandon the idea that informed consent is required for data-based research, federal and state courts can more easily resist the application of property-like control to individual genetic data. The judicial shift away from propertizing consent will not occur overnight, but practically speaking it can only begin after the federal government takes the first step.

B. EXISTING LIABILITY RULES FOR DATA-BASED RESEARCH

A number of liability rules exist today that limit the ability of researchers to exploit individual data freely. This proposal does not seek to limit or change these existing liability rules, but rather seeks to augment the current system with the new liability rules proposed in Section III.C.

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234. In considering this hypothetical property-based system, we disregard for the moment existing exclusions from the informed consent requirement under federal research regulations discussed in Sections II.B and C.

235. *See infra* Section III.E.

236. In 2009, the Institute of Medicine recommended a similar revision (Recommendation I) to the HIPAA Privacy Rule for all research using health information, with the development of additional privacy protections for this information. *See* INST. OF MED., *supra* note 28, at 30.

1. Deception and Breach of Fiduciary Duty

The frequently cited case *Moore v. Regents of the University of California* is best known for holding that John Moore, a patient at UCLA Medical Center, had no property interest in cells removed from his body or the medical discoveries made using those cells.[237] But despite the court's rejection of Moore's property-based claims, it upheld claims against his physician arising from breaches of the physician's fiduciary duty.[238] In obtaining the patient's consent, "a physician has a fiduciary duty to disclose all information material to the patient's decision."[239] Moore's primary attending physician at the University of California, Los Angeles (UCLA), Dr. David Golde, allegedly failed to disclose several important pieces of information to Moore. Among these were Dr. Golde's intention to retain a portion of Moore's spleen after it was removed and that subsequent extractions of Moore's blood and tissue were performed for research rather than treatment purposes.[240] These facts were sufficient to allow Moore to maintain an action for breach of fiduciary duty against Dr. Golde without giving Moore a property interest in his tissue or resulting data.[241] As the court explained, "it [is not] necessary to force the round pegs of 'privacy' and 'dignity' into the square hole of 'property' in order to protect the patient, since the fiduciary duty and informed-consent theories protect these interests directly by requiring full disclosure."[242]

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the plaintiffs also brought claims for breach of fiduciary duty alongside claims asserting conversion of genetic material and data.[243] But unlike the plaintiff in *Moore*, the plaintiffs in *Greenberg* asserted their fiduciary duty claims against the medical researchers who utilized the data that they provided rather than an attending physician.[244] Finding this to be a meaningful distinction, the court in *Greenberg* declined to recognize a fiduciary relationship between medical researchers and individual tissue and data donors.[245] The plaintiffs in the *Havasupai* case also brought a claim for breach of fiduciary duty against ASU and its researchers.[246] However, the case settled before adjudication of this claim.[247]

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237. 793 P.2d 479, 492 (Cal. 1990).

238. *Id.* at 486. In California, as in most states, a patient's informed consent is required for medical treatment. *Id.* at 483 (citing Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972)).

239. *Id.*

240. *Id.* at 485–86.

241. *Id.* at 486.

242. *Id.* at 491. Although requiring disclosure of information in a manner consistent with the informed consent requirement, the fiduciary obligation of a healthcare provider does not give patients property-like control over data resulting from their care.

243. 264 F. Supp. 2d 1064, 1066 (S.D. Fla. 2003).

244. *Id.* at 1072.

245. *Id.*

246. Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063, 1069 (Ariz. Ct. App. 2008).

247. *See supra* note 138 and accompanying text.

These cases demonstrate that breach of fiduciary duty claims against medical practitioners and researchers are potentially available to individuals who believe that data they provided has been used in a manner that violates a relationship of trust. Although such claims will not always be successful and will only arise when patients become aware of data misuse,[248] they are likely to vindicate individual rights at least in particularly egregious cases such as *Moore*. And although fiduciary claims may not be available against researchers lacking a direct healthcare relationship with a patient, as they were not in *Greenberg*, this result is consistent with the general parameters of fiduciary law.

2. Other Common Law Actions—Fraud and Deceit

In addition to actions for breach of fiduciary duty, additional common law actions exist for deception, misrepresentation, and fraud committed to induce individuals to partake in medical experimentation. Such actions can be brought when researchers obtain genetic material and data from research participants under false pretenses, with inadequate disclosure of their intentions, or in an otherwise deceptive manner. Thus, the allegedly deceptive actions of the UCLA researchers in *Moore* might also have given rise to claims of fraud and deceit.[249] The plaintiffs in the *Havasupai* case also raised allegations of fraud in their complaint, but the case settled before this claim was adjudicated.[250] Though often overlooked in the literature, these conventional causes of action can be effective to address the most egregious abuses of experimental data acquisition and use.

3. Prohibiting Genetic Discrimination

In 2008, Congress enacted the Genetic Information Nondiscrimination Act (GINA).[251] Among other things, GINA prohibits discrimination by employers and health insurers based on an individual's genetic profile.[252] Senator Edward Kennedy, who sponsored the legislation, called GINA "the first major new civil rights bill of the new century."[253]

The first legislative proposals to curtail genetic discrimination were made in 1995.[254] GINA, however, was not enacted until thirteen years later. In the

248. *See infra* Section III.D.1.

249. In fact, Moore did plead a claim sounding in fraud and deceit, though the California Supreme Court did not address this claim on appeal. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482 n.4 (Cal. 1990). If Moore had been able to prove the allegations in his complaint, an action for common law fraud and deceit might have had a reasonable chance of success. *See id.* at 513 n.14 (Mosk, J., dissenting) (enumerating allegedly false and misleading statements by the defendants).

250. *Havasupai Tribe*, 204 P.3d at 1069.

251. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-223, 122 Stat. 881 (2008) (codified as amended in scattered sections of 29 and 42 U.S.C.).

252. *Id.*

253. Kathy L. Hudson, M.K. Holohan & Francis S. Collins, *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW. ENG. J. MED. 2661, 2662 (2008).

254. *Id.* at 2661.

intervening years, many states enacted their own legislation prohibiting genetic employment and health insurance discrimination to some degree.[255] Whereas some advocates hoped that GINA would prohibit more forms of discrimination, the political realities of the day dictated a more modest scope for the final legislation.[256]

Unlike the informed consent requirements under the Common Rule and HIPAA, GINA does not require that a user of individual genetic data explain the proposed use and seek the individual's consent to that use. Instead, it simply prohibits certain categories of undesirable conduct (discrimination based on genetic information) and provides legal remedies for noncompliance.[257] This approach is similar to other antidiscrimination legislation (for example, employment or housing), which directly prohibits the discriminatory conduct.

The Equal Employment Opportunity Commission (EEOC) has estimated that 333 claims of employment discrimination were brought under GINA in 2013.[258] Although the number of claims remains small in comparison to the 90,000 employment discrimination cases brought annually in the United States, the number of GINA claims has steadily increased since the law's effectiveness in 2010.[259] Likewise, a number of these cases have resulted in settlements or the payment of compensation to the victims after mediation.[260]

The most significant GINA penalty to date was a jury verdict in a private enforcement action brought by two Georgia employees against their employer, Atlas Logistics.[261] Atlas, an Atlanta-based warehouse operator, requested DNA samples from its employees as part of an investigation to determine who was defecating in one of its warehouses. Two employees who were exonerated in the investigation brought suit against Atlas under GINA for being forced to submit

255. *See* Prince, *supra* note 23, at 210–11 (describing state statutes); Mark A. Rothstein, *Putting the Genetic Information Nondiscrimination Act in Context*, 10 GENETICS MED. 655, 655 (2008).

256. GINA does not prohibit discrimination in the areas of life, disability, or long-term care insurance, by the military or employers with fewer than fifteen employees, or against individuals already diagnosed with a genetic disease. Genetic Information Nondiscrimination Act of 2008 § 2(5), 122 Stat. at 882–83; *see also* Hudson, Holohan & Collins, *supra* note 252, at 2662; Rothstein, *supra* note 254, at 656. Today, the Affordable Care Act prohibits discrimination by health insurers on the basis of any preexisting condition, including the results of genetic tests, thus addressing the gap for individuals with existing genetic diseases. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 26, 29, 30 and 42 U.S.C.). Likewise, a number of states including California have enacted prohibitions on genetic discrimination in life and disability insurance, closing these gaps. *See Beyond GINA, States Build Patchwork of Protections*, GENOMEWEB, (Aug. 22, 2012), https://www.genomeweb.com/beyond-gina-states-build-patchwork-protections [https://perma.cc/LZ4A-EHJK] [hereinafter GENOMEWEB].

257. *See* Genetic Information Nondiscrimination Act of 2008 §§ 202, 207, 122 Stat. at 907, 914.

258. Robert C. Green, Denise Lautenbach & Amy L. McGuire, *GINA, Genetic Discrimination, and Genomic Medicine*, 372 NEW ENG. J. MED. 397, 397–98 (2015).

259. *See* GENOMEWEB, *supra* note 255 (reporting 245 GINA employment claims in 2011 and 210 in 2010).

260. *Id.*

261. Lowe v. Atlas Logistics Grp. Retail Serv. (Atlanta), LLC, 102 F. Supp. 3d 1360, 1360 (N.D. Ga. 2015).

to the DNA test. Atlas was found to have violated GINA, and the employees were awarded approximately $2.2 million by the jury.[262]

Although GINA regulates the use of genetic information by insurers and employers, not by researchers, this statute is a good example of a direct prohibition on the use of genetic information that could potentially be adapted for use in the research context.

4. Contracting for Greater Protection and Participation

As discussed above, the propertized character of human genetic data may threaten to produce an anticommons effect.[263] Some organizations, however, have implemented contractual strategies to address these issues while also engaging patients and families in the research enterprise.[264] Perhaps the best known example of this approach is PXE International (PXEI), an organization founded in 1995 by the parents of children suffering from a rare and potentially lethal genetic disorder called *pseudoxanthoma elasticum* (PXE).[265] After discovering that little coordinated research was being conducted on PXE, Sharon and Patrick Terry mobilized a small community of PXE patients and family members to support research on the disease. The group they founded, PXE International (PXEI), engages in research funding, educational outreach, public awareness, and other disease advocacy activities. In addition, PXEI assembled a biorepository containing tissue and blood samples from PXE patients and entered into contractual relationships with academic institutions conducting research on PXE.[266]

Through PXEI, patients and advocates were able to intervene in research about a disease of interest to them.[267] They collaborated directly on research

262. Gina Kolata, *Georgia: $2.2 Million Penalty for Illegal DNA Testing*, N.Y. TIMES (June 22, 2015), http://www.nytimes.com/2015/06/23/us/georgia-dollar2-2-million-penalty-for-illegal-dna-testing.html?_r=0 [https://perma.cc/98L7-6Z3M].

263. *See supra* Section II.D.

264. A dozen years ago, Jerry Reichman and Paul Uhlir recognized that a proliferation of copyright, database, trade secret, and other intellectual property rights threatened to limit the commons of scientific data available for use by researchers. Reichman & Uhlir, *supra* note 10. To address this threat, they proposed the creation of a "contractually reconstructed research commons." *Id.* at 416–57. The landscape they envisioned was one in which a network of contractual instruments (including waivers of applicable intellectual property rights) would create an open legal environment in which research could be conducted more or less freely.

265. *See* Sharon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 NATURE REV. GENETICS 157, 157–58 (2007); Sharon F. Terry & Charles D. Boyd, *Researching the Biology of PXE: Partnering in the Process*, 106 AM. J. MED. GENETICS 177, 180 (2001).

266. Terry et al., *supra* note 264, at 162; Terry & Boyd, *supra* note 265, at 179–80.

267. PXEI served as the interface between the research community and the PXE patient community, among other things coordinating informed consent for all samples deposited in the biorepository. Terry & Boyd, *supra* note 264, at 181. The PXE biorepository became an invaluable resource for genetic investigations of PXE and eventually aided in the identification of the gene responsible for the disorder. When a patent application was filed covering the gene and its mutations, PXEI members were listed as coinventors and PXEI became the assignee and controller of the patent. Terry et al., *supra* note 264, at 161.

questions, became coauthors of scientific papers, and came to control the commercialization of the patents covering the relevant genes. PXEI is frequently cited as an exemplar of effective collaboration between lay and scientific groups.[268] Though Terry and others emphasize the collaborative nature of the relationship between PXEI and its research partners, the legal underpinnings of the relationship were established through contract law.[269] The relevant contracts specified, among other things, the "acceptable uses of sole and joint data and materials, as well as . . . specific timelines for public release of new jointly generated data."[270]

Of course, contractual solutions may not be viable on the scale of programs such as PMI and raise many of the same questions and issues as the informed consent paradigm, not to mention emphasizing property-like interests in genetic data even more strongly. However, such arrangements may offer attractive alternatives when closely defined interest groups wish to secure greater protection and rights for themselves than default legal mechanisms provide.

C. NEW LIABILITY RULES FOR GENETIC DATA

Though current liability rules offer a range of protections for individual genetic data, they do not yet offer a complete solution. And although, as discussed above, propertizing consent has likely gone too far toward granting control over data to individuals at the expense of research, the elimination of all the protective features of consent is neither feasible nor desirable. Accordingly, this Section outlines possible additional liability rules directed toward filling the gaps in current liability rules and protecting the most critical individual interests in genetic data. Although this short summary is not intended to be comprehensive, or to explore fully the range of legal options that would be necessary to impose a liability-based regime for genetic research regulation, it offers examples of the types of rules that might be implemented under such a system.[271]

1. Outlaw Genetic Discrimination

Perhaps the lowest hanging fruit when considering additional liability rules to protect individual interests arising from the use of genetic data is finishing the job begun by GINA and ending all unfair discrimination on the basis of genetic

268. *See, e.g.*, Ségoléne Aymé, Anna Kole & Stephen Groft, *Empowerment of Patients: Lessons From the Rare Diseases Community*, 371 LANCET 2048, 2050 (2008).

269. *See* Terry et al., *supra* note 265, at 161 box 2 (describing terms of a Memorandum of Understanding used to formalize the terms of collaboration between an advocacy group and a research institution).

270. *Id.*

271. The comprehensive delineation of such a rules regime will be a significant undertaking and, hopefully, the subject of significant future research.

information.[272] As noted above, GINA currently prohibits discrimination in health insurance.[273] Advocates have argued that the Act should also prohibit genetic discrimination as to life, disability, and long-term-care insurance.[274] Analytically, there is little difference between the types of discrimination included and omitted from GINA, and it appears that the omission was more a matter of political expediency than any principled argument. Accordingly, GINA should be expanded to cover these additional forms of insurance.[275]

Another notable exclusion from GINA is the U.S. military, which is the largest employer in the world.[276] An easy extension of GINA would be to cover the military under its prohibitions on employment discrimination. Likewise, GINA applies only to employment discrimination by private sector employers with more than fifteen employees.[277] On one hand, small businesses are exempt from many regulatory schemes that are perceived to impose disproportionate recordkeeping and procedural burdens on businesses lacking the resources to comply with them. On the other hand, it is not clear why small businesses should be permitted to engage in a form of employment discrimination that has otherwise been condemned and that requires affirmative action (accessing and considering genetic test data in employment decisions) from the business.

Other forms of genetic discrimination may also be suitable for regulation under GINA or similar legislation. One example is discrimination in education. In *Chadam v. Palo Alto Unified School District*, the parents of a child carrying genetic markers for cystic fibrosis, but who was not yet symptomatic, sued the school district for transferring him to a different school.[278] The parents brought claims under the Americans with Disabilities Act (ADA) and the First Amendment, among other laws. Though their case was dismissed by the district court,

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272. Susan Wolf, among others, has criticized the legislative focus on genetic discrimination as "mired in a first-stage understanding of equality theory" and too narrow to address underlying systemic failures to remedy broader racial, gender, and other disparities. Susan M. Wolf, *Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism*, 23 J.L. MED. & ETHICS 345, 345 (1995).

273. *See supra* note 252 and accompanying text.

274. *See, e.g.*, Hudson, Holohan & Collins, *supra* note 253, at 2663 ("It may well be time for a thoughtful evaluation of these other realms that are likely to be touched by the swift advance of genomic science."); Prince, *supra* note 23, at 201–11.

275. Some commentators have pointed out that many states have already sought to fill these gaps in GINA's coverage through state insurance legislation. *See supra* note 256 and accompanying text. Nevertheless, there are several advantages to a uniform system of federal regulation that make an amendment to GINA desirable. For example, consistent treatment across all fifty states is desirable for employee mobility and consistency of healthcare coverage.

276. *See* Sue Chang, *U.S. Military Is the Largest Employer in the World*, MARKETWATCH (June 17, 2015), http://www.marketwatch.com/story/us-military-is-the-largest-employer-in-the-world-2015-06-17 [https://perma.cc/DR9B-HS94].

277. *See Facts About the Genetic Information Nondiscrimination Act*, U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, https://www.eeoc.gov/eeoc/publications/fs-gina.cfm [https://perma.cc/9FZF-G4L7].

278. Order, No. C 13-4129 CW, 2014 WL 325323, at *1 (N.D. Cal. Jan. 29, 2014) (dismissing the claim with prejudice).

the matter is currently on appeal to the Court of Appeals for the Ninth Circuit.[279]

2. Prohibit Reidentification

One of the principal threats that has been identified from the use, sharing, and disclosure of human genetic information is the possibility that even deidentified, anonymized data will be reassociated with the identity of individual donors.[280] Today, there is no general legal prohibition on reidentification of individuals from their genetic data. Concerns with this practice exist whether reidentification is done for nefarious purposes or not. The informed consent doctrine requires that researchers inform research participants of these risks and that individuals voluntarily consent to studies of their genetic information with an understanding of these risks. As a result, individuals who are particularly sensitive to the risks of reidentification are less likely to participate in research. This group of individuals may be more likely to carry genetic anomalies meriting study, and their exclusion from the research could lead to systematic consent bias that is detrimental to all participants and the general scientific community.[281]

Unlike the informed consent doctrine, a simple liability rule[282] could directly address the risk of reidentification by prohibiting the reidentification of individual human subjects from deidentified genetic data.[283] Any person or entity found to have attempted or undertaken such reidentification would be subject to civil penalties, damages, and possibly criminal prosecution.[284] Exceptions would have to be considered in the case of law enforcement, national security, public health, and similar situations. To limit the abuse of these exceptions, some form of independent review and authorization mechanism could be put in place, just as the issuance of a search warrant requires approval by a judicial officer.

But even with such an administrative procedure in place, a liability rule is likely to be more efficient than obtaining consent from every research participant. Legally prohibiting the reidentification of deidentified human genetic data would go a long way toward preventing many of the nefarious uses of genetic information that privacy advocates fear.

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279. *See* Jennifer K. Wagner, *Genetic Discrimination Case Against School District Is Appealed to Ninth Circuit,* GENOMICS LAW REP. (Feb. 2, 2016), http://www.genomicslawreport.com/index.php/2016/02/02/genetic-discrimination-case-against-school-district-is-appealed-to-ninth-circuit/ [https://perma.cc/9SU6-A78H].

280. *See supra* Section II.C.

281. *See supra* notes 184–86 and accompanying text (discussing selection bias).

282. Such a rule could be implemented at the state or federal level. There are advantages and disadvantages of each approach. A federal rule would offer uniform treatment across the country, but state rules would allow varying levels of protection to be implemented based on local preferences.

283. The detailed contours of such a rule would need to be developed further.

284. For further discussion of the question of monitoring responsibility and costs, see *infra* Section III.D.1.

3. Prohibit Nonresearch Use

Numerous studies have shown that many members of the public are willing to permit their genetic data to be used in furtherance of biomedical research.[285] Concerns arise, however, with the possibility that data will be used for purposes such as insurance rating, job qualification, or marketing. To be sure, GINA and state antidiscrimination statutes prohibit discrimination on the basis of genetic information.[286] However, another approach to preventing these uses of genetic information is to ban all nonresearch uses of human genetic data and, conversely, to permit all legitimate biomedical research uses.

Developing such a regulatory structure raises nearly as many questions as it resolves. For example, who would decide what constitutes legitimate research use? Would commercial (for example, pharmaceutical) research be permitted under this broad rubric? It is also questionable whether certain types of controversial research (for example, on embryonic stem cells, hybridization of species, genetically modified organisms, human organ cloning, birth control, and embryonic trait selection) should be permitted wholesale or whether limitations on the use of individual data for morally objectionable research should be contemplated. But at the margins, there should be little controversy over practices that should not qualify as legitimate research, such as transfers of data to direct marketing firms, private investigators, and the like. Thus, despite the inherent questions raised by such an approach, it is another liability-type avenue to protecting human research participants without giving them property-like control over their data.

4. Enhance Data Security

The HIPAA Security Rule currently establishes minimum data security standards that must be met by organizations holding PHI in electronic form.[287] Notwithstanding the existence of the HIPAA Security Rule, there have been numerous significant data security breaches involving PHI over the past decade, including breaches at research institutions.[288] Moreover, in its 2009 report on the HIPAA Privacy Rule, the Institute of Medicine (IOM) identified several important gaps in the HIPAA Security Rule. These included both limitations in the organizations covered by the rule, as well as deficiencies in the security standards that it mandates (for example, not requiring file encryption).[289]

Accordingly, in its 2009 report, the IOM recommended supplementing the HIPAA Security Rule with new federal regulations that would "require researchers, institutions, and organizations that store health data to establish strong data

285. *See supra* note 183.

286. *See supra* notes 252–56 and accompanying text.

287. 45 C.F.R. pts. 160, 162, & 164 (2003). *See* INST. OF MED, *supra* note 28, at 94–100.

288. *See* INST. OF MED, *supra* note 28, at 95–96 (listing major research security breaches from 2006–2008).

289. *See id.* at 94, 97–99.

security safeguards."[290] The suggested security measures include, among other things, appointing data security officers, encrypting electronic files, including data security experts on IRBs, implementing breach notification requirements, and protecting against security breaches.[291]

Regulations such as these would be sensible by any standard. But in terms of obviating the need for propertizing informed consent rules, they could play a particularly important role by alleviating individuals' concerns regarding the safety and security of genetic data that they provide. With sufficient security regulations in place, and a demonstrable decline in security breaches, individuals could become more comfortable with providing their genetic data to researchers, thus reducing the need for them to retain property-like control over that data.

D. WHO BEARS THE COST OF LIABILITY RULES?

1. Monitoring Costs

One of the challenges of designing any rules system is identifying and fairly placing the burden of monitoring compliance with, and enforcement of, the rules. As described above, property systems create restrictions on access, whereas liability systems create penalties for misuse.[292] This distinction results in different monitoring costs for the affected parties. In a property rule system in which access to a propertized resource is conditioned on obtaining the property owner's consent, compliance monitoring is often straightforward. Anyone entering a landowner's property without paying the required toll can be assumed to have violated the rule. And if the landowner is permitted to erect tollbooths, access is likely to be strictly controlled, with few violations occurring. Liability rule systems, on the other hand, require greater monitoring to determine whether violations have occurred after the fact (for example, driving above the speed limit).

At a high level, the same is true with respect to data-based research. If an individual refuses to permit the collection of her DNA (access), then no monitoring of the researcher's use will be required. But once initial access is granted,[293] it becomes difficult for the individual to determine whether the researcher is acting in accordance with the consent that was given, and violations normally become known only through chance. Often, identification of consent violations does not occur until years after the relevant study is com-

290. *Id.* at 30 (Recommendation I).

291. *Id.* at 55 (Recommendation III.A).

292. *See supra* notes 231–33.

293. For purposes of this discussion, I assume that genetic material and data have already been collected through some process that has not violated the individual's right of bodily integrity and that complies with informed consent requirements for invasive procedures. Although not unprecedented, the widespread coerced collection of human DNA by the state (for example, mandatory saliva swabs as part of drivers licensure or voter registration procedures) presents additional ethical and legal issues that are beyond the scope of this article.

pleted and results are published. In *Havasupai*, for example, the tribe did not learn that their DNA was being used in studies beyond diabetes research until one tribe member serendipitously attended the doctoral dissertation of a junior researcher who had used some of the Havasupai genetic material in a study of ancient human migratory patterns.[294]

Today, the primary responsibility for safeguarding individual rights in research studies lies with the IRBs of research institutions. IRB approval is required before a research study can commence and often before federal grant funding is sought.[295] IRBs ensure that the proposed research plan includes adequate means to obtain informed consent from research participants and will not approve a study until IRB members are satisfied that this plan is adequate. Some critics have complained that this process itself is overly burdensome and inhibits research.[296] But even when IRBs operate efficiently, they are not equipped to monitor ongoing compliance with research protocols, nor do they typically ensure that researchers have obtained informed consent in the manner originally proposed.

Moreover, neither obtaining IRB approval nor complying with an IRB-approved consent program ensures that individual research participants will not later object to the use of their data and bring suit. Thus, the IRB responsible for overseeing the studies in *Havasupai* approved the relevant consent, and the researchers proceeded only after obtaining the necessary consents.[297] This did not stop the plaintiffs from arguing later that the consent sought and obtained was inadequate.

Because IRBs are usually constituted by individuals employed by the institutions conducting research, they cannot be viewed as objective watchdogs of research conduct, as might governmental overseers. Thus, though IRBs purport to safeguard the interests of research participants, the principal burden of monitoring and enforcement really falls on research participants themselves. As a result, unlike landowners who may erect tollbooths at the entrance to their properties, "owners" of human DNA have no practical way to prevent or monitor the use of their genetic data after it is collected.

In this regard, the monitoring burden of individuals under the existing property rule regime is similar to that under the proposed liability rule regime. That is, absent some form of governmental monitoring and enforcement function, which does not exist today and is unlikely to emerge in the foreseeable future, individuals bear the burden of identifying rule breaches and asserting their rights.

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294. Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063, 1067 (Ariz. Ct. App. 2008).

295. IRB requirements are contained in both the Common Rule and HIPAA Privacy Rule. 45 C.F.R. § 46.101 (2009); 45 C.F.R. pt. 160, 162, 164 (2003).

296. *See, e.g.*, Frederic L. Coe, *The Costs and Benefits of a Well-Intended Parasite: A Witness and Reporter on the IRB Phenomenon*, 101 NW. L. REV. 723 (2007).

297. *See* Mello & Wolf, *supra* note 132, at 204 (discussing ASU consent form); Wolf, *supra* note 20, at 121 (same).

2. Enforcement Costs

In addition to the cost of monitoring compliance with a rules regime, there is a cost associated with remedying breaches of those rules. That is, once a breach is identified, how costly is it for the violator to remedy the breach? In an equitable system, the cost of remedying a breach should not be grossly disproportionate to the harm caused by the breach. Stewart Sterk illustrates this point using copyrights in musical compositions and other works.[298] Sterk first assumes that the "social harm of infringement can be measured by the harm to the copyright holder minus the infringer's avoidance cost."[299] In his example, the producer of a musical work may infringe the copyright in another work. If the infringement is of a small portion of the prior work, as it was with George Harrison's unconscious infringement of three notes of the Chiffons' song "He's So Fine," the harm to the owner of the prior work could be small, yet the cost of removing the infringing material from every copy of the new work after it has been released and distributed could be extremely high. As Sterk explains, "removal costs may be high because once infringement occurs, the infringer may have no practical mechanism for segregating infringing from non-infringing material."[300] Accordingly, Sterk argues that in cases involving low social harm and high removal costs, liability rules that impose monetary noncompliance penalties are more efficient than property rules that impose disproportionate removal costs.[301]

An analogous argument can be made with respect to research use of individual genetic data. As discussed above, the cost of removing individual data from a research database may be high, whereas actual harm to individuals if the data is used for legitimate research purposes may be low. Of course, this analysis requires a highly subjective judgment regarding the injury caused by undesirable research uses of individual genetic data. But the use of liability versus property rules itself does not dictate the level of monetary recovery available for violations of liability rules. It only represents an acknowledgement that, on the whole, removal costs are likely to be higher than the cost of individual injuries, thereby recommending a liability rule approach over a property rule approach to maximize social welfare.

298. Stewart E. Sterk, *Property Rules, Liability Rules, and Uncertainty About Property Rights*, 106 MICH. L. REV. 1285, 1328–29 (2008).

299. *Id.* at 1328.

300. *Id.* at 1329 ("Removal costs—the cost of recording a new version of a song, excising a scene from a big-budget movie, or republishing a novel without the infringing content—may be quite high.").

301. *Id.* Under such frameworks, penalties must be meaningful enough to deter infringement and avoid excessive levels of "efficient" breach, particularly in the case of rules relating to medical research and genetic data. *See infra* Section III.E regarding the selection and calibration of penalties in this area.

E. REMEDIES FOR BREACHES OF LIABILITY RULES

As described by Calabresi and Melamed, the defining feature of liability rules, as opposed to property rules, is that the offending use may continue, subject to payment of the applicable penalty.[302] Such rules are desirable when it is socially beneficial to allow an activity to continue, despite the harm that may be inflicted on some parties. Thus, a cement plant that is a nuisance to its neighbors may be permitted to continue operation, so long as the neighbors are compensated for the injury caused to them.[303] Likewise, biomedical research using aggregated genetic data should be permitted to continue, even if some researchers have violated applicable rules pertaining to the collection or use of that data. The relevant question then becomes what penalty to impose on those noncompliant researchers.

1. Compensatory Damages

Compensatory monetary damages are the standard remedy for violations of liability rules. Compensatory damages serve to compensate injured parties for both past and future injuries flowing from a triggering action.[304] Although it may be difficult to place a monetary value on violations of restrictions on the use of genetic data, it is not impossible. Existing liability regimes relating to breach of fiduciary duty, fraud and deception, and discrimination offer a large body of damages case law upon which to draw. Reference to these other liability regimes can be found in the damages theories advanced by the plaintiffs in past cases alleging the misuse of genetic material and information. As has been widely reported, the Havasupai Tribe initially sought damages of $50 million from ASU and its researchers.[305] The plaintiffs in *Greenberg* sought the disgorgement of all patent royalties received by the hospital researchers as well as a return of amounts contributed by the plaintiffs to the allegedly impermissible research.[306] And in *Lowe v. Atlas*, two employees won a $2.2 million jury verdict against their employer for requesting their DNA in violation of GINA.[307] Thus, there are ample legal theories available to support claims for compensatory damages with respect to violations of rules concerning the use of genetic data.[308]

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302. *See supra* notes 231–33 and accompanying text.

303. Boomer v. Atlantic Cement Co., 257 N.E.2d 870, 875 (N.Y. 1970).

304. *See* RESTATEMENT (SECOND) OF TORTS § 903 (AM. LAW INST. 1977).

305. The parties settled with a payment of $700,000, plus return of the relevant genetic material. *See supra* note 138.

306. Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1068 (S.D. Fla. 2003).

307. *See supra* note 260 and accompanying text.

308. Admittedly, the common law of tort is generally less amenable to the award of compensatory damages for nonphysical than physical injuries. *See* PROSSER AND KEETON ON THE LAW OF TORTS § 12 (W. Page Keeton et al. eds., 5th ed. 1984) ("[I]t has been said that mental consequences are so evanescent, intangible, and peculiar, and vary to such an extent with the individual concerned, that they cannot be anticipated, and so lie outside the boundaries of any reasonable 'proximate' connection with the act of

2. Punitive Damages and Penalties

In addition to compensatory damages, punitive damages are sometimes authorized by statutory frameworks that seek to deter particularly undesirable forms of conduct. For example, the imposition of treble damages is authorized for certain violations of antitrust law,[309] and enhanced or multiple damages are authorized under the Patent Act for conduct including "willful" infringement.[310] It will be up to the courts and policymakers on a case-by-case basis to determine whether punitive damages are warranted by violations of the proposed liability rules pertaining to genetic data use.

3. Injunctive Relief

Monetary damages, even with the possibility of punitive damages, may not always be adequate to redress a wrong committed when a liability rule is violated. In many cases, the wrong itself, and the ongoing injury that it causes, must be abated. For example, violations of prohibitions on genetic discrimination in employment should result in a reevaluation of the relevant candidate without regard for the impermissible (discriminatory) information. Injunctive relief in discrimination cases is relatively well understood.[311] Likewise, violations of rules prohibiting reidentification of individuals from their genetic data can be enforced through deletion of the reidentified data from relevant databases.

It is important to emphasize, however, that injunctive relief awarded to redress violations of the proposed liability rules should not prohibit permissible research using the affected genetic data. This research should be permitted to continue in furtherance of the public interest in medical research. This is one of the principal differences between the proposed liability rule regime and the current propertized consent regime. In the former, legitimate research is allowed to continue, notwithstanding the award of damages and injunctive relief with respect to the impermissible conduct. In the latter, the "owner" of genetic data has the right to stop all uses of the data, whether or not they result in injury or harm (that is, the "harm" is deemed to stem from any nonconsensual use of data). Allowing permissible research to continue will yield social welfare benefits in terms of scientific and medical progress, while enabling specific impermissible activity to be curtailed.

4. Administrative Penalties

In cases of repeat offenders or particularly egregious conduct, relevant funding agencies (for example, the NIH) may impose administrative penalties

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the defendant."). This bias against compensation for nonphysical injuries could result in relatively low monetary rewards for breaches of data-based research restrictions, but if it is generally perceived that an injustice is worked by the paucity of such rewards, the situation can be addressed through appropriate legislative action.

309. 15 U.S.C. § 15(a) (2012).

310. 35 U.S.C. § 284 (2012).

311. *See, e.g.*, GEORGE RUTHERGLEN, EMPLOYMENT DISCRIMINATION LAW 181–82 (3d ed. 2009).

directly on noncompliant researchers or institutions. These penalties could take the form of debarment procedures, such as those imposed on government contractors that violate federal procurement rules[312] or suspension of individuals from association with broker-dealers after violating the federal securities laws.[313] That is, offending researchers could be barred, either permanently or for a fixed duration, from further human subjects research or any federally funded grant programs. Likewise, medical professionals could be subject to revocation or suspension of their medical licenses.

In cases that reveal a broader institutional disregard for individuals, penalties could be imposed at the institutional level. Although rare, there is precedent for such institutional penalties when an institution is deemed to have acted with disregard for public safety or welfare. For example, institutional penalties have been applied in the area of securities regulation when firms have exhibited deliberate and pervasive disregard for compliance with applicable rules.[314] Thus research institutions or hospitals could themselves be subject to heightened scrutiny, grant debarment, license review, and other relevant administrative penalties.

If offenders are insurers, employers, or other nonresearch institutions, administrative penalties could be developed by state insurance regulators, the EEOC, or other relevant agencies. In all of these cases, as discussed above in terms of injunctive relief, administrative penalties should not include the deletion of individual genetic data from biorepositories or research databases. Socially beneficial research utilizing these resources should be permitted to continue under all circumstances.

CONCLUSION

Under U.S. law, there is no cognizable property interest in facts. Yet the doctrine of informed consent has created a de facto property interest in human genetic data that permits individuals to exert strong property-like rights to prevent the usage of data for research purposes and, in extreme cases, to cause the deletion and destruction of valuable data resources.

The requirement to obtain informed consent for the conduct of data-based research has outlived its usefulness. Risks to individuals are comparatively low, and the potential social benefits from enabling biomedical research are great. Accordingly, this Article proposes a shift in thinking about genetic data. Using the property-liability dichotomy introduced by Calabresi and Melamed, it envisions a regime in which the consent-based requirements for data-based research

312. 48 C.F.R. subpt. 9.4 (2013) (debarment in government procurement relationships); 2 C.F.R. pt. 180 (2015) (debarment in nonprocurement relationships).

313. 15 U.S.C. § 78o(b)(4)(C)–(D) (2012).

314. One of the most extreme examples of institutional liability for rule violations was the criminal indictment of the Arthur Andersen firm in connection with its role in the Enron scandal. *See* Kurt Eichenwald, *Enron's Many Strands: The Investigation; Andersen Charged With Obstruction in Enron Inquiry*, N.Y. TIMES, Mar. 15, 2002, at C6.

under the Common Rule, the HIPAA Privacy Rule, and similar regulations would be replaced by a liability rule regime prohibiting identified research abuses. With sufficiently meaningful penalties for violation of these restrictions at both the institutional and individual levels, individual privacy and autonomy will continue to be protected, while data-based research can proceed without the hindrances posed under a propertizing consent regime.