SECURING SEQUENCES: ENSURING ADEQUATE PROTECTIONS FOR GENETIC SAMPLES IN THE AGE OF BIG DATA

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Bulk collection of our personal data is increasingly common. Our internet browser history leads to personalized, targeted advertising; credit card companies aggregate billions of our collective transactions to gain insight into our spending patterns; and, as recently revealed, the National Security Agency engaged in the widespread collection of our telephone data without our knowledge or consent. But what if the data being collected, stored, shared, and used without our knowledge or consent is arguably the most personal of all data—our unique genetic sequence? In ways underreported and underexamined, the genetic information of nearly every American is likely to have been collected and stored without consent for possible subsequent use.

This Article is the first to recognize the range of routine interactions—a trip to the doctor's office, the birth of a newborn, a decision to try direct-to-consumer genetic testing, even wandering through a crime scene—that can lead to the collection and storage of our genetic samples. With scant protection or third-party review, these collected samples can be used for a potentially limitless range of nonconsensual future uses, including in research, commercialization, and criminal justice. The justifications proffered for the ongoing nonconsensual collection and use—that the genetic samples have been abandoned, that they have been de-identified so are unlikely to cause harm, that they are so useful that obtaining informed consent could stymie important biomedical progress, and that recognizing any ongoing interests affords donors undue control—do not withstand closer scrutiny.

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Accordingly, this Article calls for the re-invigoration of the longstanding ethical safeguards of informed consent and third-party review—safeguards that are often discarded in the collection and use of genetic data. In addition to promoting the ethical collection and use of genetic data, these safeguards protect against potential backlash should individuals discover that the status quo permits the mass, surreptitious, nonconsensual collection and use of their genetic data—a discovery that has already led to the incineration of millions of collected samples.

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INTRODUCTION

The era of big data is inevitably upon us and society is still grappling with what should be considered the permissible, nonconsensual uses of an individual's data. Recent events involving the nonconsensual use of data previously thought to be private—including Facebook's manipulation of user feeds in research,[1] targeted advertising based on internet browsing history,[2] and the National Security Agency's collection of data subsequently exposed by Edward Snowden[3]—have instigated national conversations, and in some cases even backlash, as we grapple with the implications of this era of big data.

But what if the data being collected, stored, shared, and used without consent is arguably the most personal of all data—your individual genetic sequence, that "kaleidoscope of identity . . . that define[s] one's sense of self"?[4] The question is not merely hypothetical. In ways underreported and underexamined, the genetic information of nearly every American is likely to have been collected and stored without consent for a potentially limitless range of future uses. Today, a decision to submit blood for a blood test, or to allow a newborn to participate in a national public health screening, could lead to the storage of that individual's entire genetic sequence in databases that are accessible to pharmaceutical companies or law enforcement. It could also mean that the hair we shed as we walk down the street could be collected, and the genetic material contained therein sequenced, for subsequent uses that we have yet to imagine. This Article examines the range of ways that genetic data is collected and used without consent, the legal and ethical implications of the move toward de facto universal inclusion in genetic databases, and the safeguards that should be

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1 *See* Adam D. I. Kramer et al., *Experimental Evidence of Massive-Scale Emotional Contagion Through Social Networks*, 111 PROC. NAT'L ACAD. SCI. 8788 (2014).

2 *See, e.g.*, Darla Cameron, *How Targeted Advertising Works*, WASH. POST. (Aug. 22, 2013), https://www.washingtonpost.com/apps/g/page/business/how-targeted-advertising-works/412.

3 *See, e.g.*, Glenn Greenwald, *NSA Collecting Phone Records of Millions of Verizon Customers Daily*, GUARDIAN (June 6, 2013, 6:05 AM), http://www.theguardian.com/world/2013/jun/06/nsa-phone-records-verizon-court-order; *see also* Ewen Macaskill & Gabriel Dance, *NSA Files Decoded: Edward Snowden Surveillance Revelation Explained*, GUARDIAN (Nov. 1, 2013), http://www.theguardian.com/world/interactive/2013/nov/01/snowden-nsa-files-surveillance-revelations-decoded#section/1.

4 Albert E. Scherr, *Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting*, 47 GA. L. REV. 445, 484 (2013).

implemented to ensure that individuals are adequately protected—safeguards that promote trust in the enterprise and protect against potential backlash.

Part I of this Article considers the implications of the move toward universal inclusion in genetic databases. Part II examines the ways that genetic data enters into databases without consent, including as medical waste, via newborn screening, through direct-to-consumer genetic testing, and by interaction with the criminal justice system. Part III considers the various nonconsensual uses of genetic data, including research, commercialization, and criminal justice. Part IV analyzes the proffered justifications for the nonconsensual collection and use of genetic data, concluding that these justifications do not withstand scrutiny. Finally, Part V sets forth steps that should be taken to ensure that the collection, storage, sharing, and use of genetic samples comply with legal and ethical guidance.

Ultimately, this Article neither wholeheartedly endorses nor categorically opposes universal inclusion in genetic databases. Rather, this Article pragmatically recognizes that, given the country's move toward universal inclusion in genetic databases, the collection, storage, sharing, and use of genetic samples should be conducted in accordance with foundational ethical principles and pertinent legal guidance.

I. UNIVERSAL INCLUSION IN GENETIC DATABASES

DNA, the code of life, is found in every cell in the human body and is unique to each of us.[5] On its own, our genetic sequence has the potential to identify us, reveal our propensity to a range of diseases, and expose sensitive health information about biologically-linked family members.[6] When analyzed together with genetic material collected from large numbers of people, and stored in databases alongside pertinent medical information, genetic data has the potential to contribute to important biomedical advances aimed at resolving the world's most pressing health concerns; this may include enabling the discovery of cures for cancer, heart disease, or autoimmune disorders.[7] The collection of population-wide genetic data is often altruistically conducted with the hope of hastening these important biomedical

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5 See PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING 2 (2012) [hereinafter PRIVACY AND PROGRESS], http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf.

6 *See id.* at 26.

7 *Id.* at 16.

advances.[8] Nevertheless, the way that population-wide genetic data is currently being collected—surreptitiously and without consent—presents a disconnect that raises serious legal and ethical concerns.

A. *The Move Toward Population-Wide Genetic Databases*

The United States is heading toward population-wide genetic databases. In his 2015 State of the Union address, President Barack Obama announced the Precision Medicine Initiative—a much-heralded plan to "leverage advances in genomics" and "pioneer a new model of patient-powered research" to "accelerate biomedical discoveries."[9] The work will be done by obtaining genetic data—along with other types of medical information[10]—from one million (or more) American volunteers.[11] The stated aim is to "improve health outcomes, fuel the development of new treatments, and catalyze a new era of data-based and more precise medical treatment."[12] The Precision Medicine Initiative is lauded as helping to bring about "a revolution in health care delivery, in which disease prediction, diagnosis, and treatment will be based on an individual patient's genetic and molecular profile."[13]

In many ways, the Precision Medicine Initiative's creation of a large-scale genetic database is the "logical next step that would build on the complete sequencing of the human genome to enhance the understanding of common diseases and improve treatments and therapies."[14] Population-wide genetic databases are considered critical to "unravel[ing] the links between genes, the disease and the

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8 *See, e.g.*, *About the Precision Medicine Initiative Cohort Program*, NAT'L INST. HEALTH, https://www.nih.gov/precision-medicine-initiative-cohort-program (last visited Apr. 11, 2016).

9 Press Release, White House Office of the Press Sec'y, Fact Sheet: President Obama's Precision Medicine Initiative (Jan. 30, 2015) [hereinafter Precision Medicine Initiative Fact Sheet], https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

10 *Id.* The proposed additional medical information includes "medical records; profiles of the patient's genes, metabolites (chemical makeup), and microorganisms in and on the body; environmental and lifestyle data; patient-generated information; and personal device and sensor data." *Id.*

11 *Id.*

12 *Id.*

13 Yvonne Stevens & Gary Marchant, *What's in It for Me?: The Question You Should Always Ask Before Giving Away Your Genetic Info*, SLATE (Apr. 8, 2015, 10:09 AM), http://www.slate.com/articles/technology/future_tense/2015/04/recruiting_people_for_genetics_studies_on_facebook.html.

14 SEC'YS ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, DEP'T OF HEALTH & HUMAN SERVS., POLICY ISSUES ASSOCIATED WITH UNDERTAKING A NEW LARGE U.S. POPULATION COHORT STUDY OF GENES, ENVIRONMENT, AND DISEASE 1 (2007) (footnote omitted).

environment."[15] Any given person shares 99.9% of their genetic sequence with any other person.[16] Accordingly, the variation in the remaining 0.1%, along with environmental and lifestyle factors, is thought to be responsible for population-wide variation in health outcomes and disease.[17] Comparing these variants across thousands or millions of samples gives researchers the statistical power to discern meaningful associations between genetic variants and disease.[18] Ultimately, "[t]he more people who contribute their data, the bigger the numbers, the truer the representation of a population, and the more powerful the results."[19]

Long before the announcement of President Obama's ambitious goal of collecting genetic material from one million individuals, the United States was already well on its way to population-wide databases—albeit surreptitiously. In 1999, the National Bioethics Advisory Commission tasked the RAND Corporation to ascertain the magnitude of this country's collection of biospecimens. In what is the most comprehensive study to date, the RAND Corporation made a "conservative estimate" that, as of the year 1999, more than 307 million tissue samples—rich sources of genetic information—from more than 178 million people were stored in U.S. repositories.[20] Accordingly, by 1999, biological samples were retained and stored from almost two-thirds of the U.S. population.[21]

These numbers are only increasing. The RAND report estimated that the number of stored samples would increase by more than twenty

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15 J.V. McHale, *Regulating Genetic Databases: Some Legal and Ethical Issues*, 12 MED. L. REV. 70, 71 (2004).

16 *See* Alice Hsieh, *A Nation's Genes for a Cure to Cancer: Evolving Ethical, Social and Legal Issues Regarding Population Genetic Databases*, 37 COLUM. J.L. & SOC. PROBS. 359, 363 (2004).

17 *Id.*

18 *See id.* at 363–64 ("By comparing populations, scientists have been able to identify the location and sequence of genetic variations that cause, or increase the risk of developing, many diseases."); Susan Scutti, *The Government Owns Your DNA. What Are They Doing with It?*, NEWSWEEK (July 24, 2014, 3:50 PM), http://www.newsweek.com/2014/08/01/whos-keeping-your-data-safe-dna-banks-261136.html ("Scientists will need lots and lots of DNA samples to translate the wealth of information found in any one genome—it is only by comparison that they can understand how, when and which genes matter, separate from the environment."); Stevens & Marchant, *supra* note 13 ("[T]his transition to personalized or precision medicine requires researchers to gain access to thousands or millions of genetic samples that will provide the statistical power to identify relationships among heredity, environment, and lifestyle factors in determining health outcomes.").

19 Stevens & Marchant, *supra* note 13.

20 *See* Elisa Eiseman, RAND Critical Technologies Institute, *Stored Tissue Samples: An Inventory of Sources in the United States*, *in* NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE VOL. II COMMISSIONED PAPERS D-1, D-38–39 (2000) [hereinafter *RAND Report*].

21 *See Historical National Population Estimates: July 1, 1900 to July 1, 1999*, U.S. CENSUS BUREAU (Apr. 11, 2000), https://www.census.gov/population/estimates/nation/popclockest.txt.

million samples each year—a number that would put the number of stored samples at upwards of 600 million.[22] Today, however, there are entire categories of genetic databases that were not included in RAND's calculation. For example, direct-to-consumer genetic testing—which has given rise to databases that contain millions of genetic samples[23]—was not yet in existence at the time of the RAND report, and the Combined DNA Index System (CODIS)—the criminal DNA database that now contains over fourteen million profiles—was in its mere infancy.[24] Scientists predict that by 2025, as many as one billion individuals worldwide will have had their genomes sequenced.[25] It is, therefore, little wonder that, as has been observed, "virtually everyone has his or her tissue 'on file.'"[26]

B. *Evolving Implications of Large-Scale Genetic Databases*

Today, in the era of big data, the implications of near-universal inclusion in genetic databases are even more profound. When the RAND report was released, collecting a biospecimen meant storing the physical sample in laboratory refrigerators or freezers, and sharing the sample required physically sending a portion to an alternate location, thereby reducing the amount of the sample held in reserve.[27] Therefore, at the time of the RAND report, the number of people who could access a specific, stored biospecimen and the genetic sequence contained therein was quite limited. Such is not the case today.

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22 *RAND Report*, *supra* note 20, at D-38. The number, however, is hard to ascertain with any precision, as there is no definitive registry of national or international biobanks. *See* Gail Javitt, *Why Not Take All of Me? Reflections on the Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens*, 11 MINN. J.L. SCI. & TECH. 713, 722 (2010).

23 For a more in depth discussion of direct-to-consumer genetic testing and the databases they have given rise to, see Section II.C.

24 *See CODIS-NDIS Statistics*, FED. BUREAU INVESTIGATION, https://www.fbi.gov/about-us/lab/biometric-analysis/codis/ndis-statistics (last visited Mar. 20, 2016) [hereinafter *CODIS-NDIS Statistics*].

25 Robert Gebelhoff, *Sequencing the Genome Creates So Much Data We Don't Know What to Do with It*, WASH. POST (July 7, 2015), https://www.washingtonpost.com/news/speaking-of-science/wp/2015/07/07/sequencing-the-genome-creates-so-much-data-we-dont-know-what-to-do-with-it.

26 Catherine K. Dunn, *Protecting the Silent Third Party: The Need for Legislative Reform with Respect to Informed Consent and Research on Human Biological Materials*, 6 CHARLESTON L. REV. 635, 643 (2012) (quoting Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005)).

27 *See* NAT'L ACADEMIES PRESS, CONDUCTING BIOSOCIAL SURVEYS: COLLECTING, STORING, ACCESSING, AND PROTECTING BIOSPECIMENS AND BIODATA (2010); Yvonne G. De Souza & John S. Greenspan, *Biobanking Past, Present and Future: Responsibilities and Benefits*, 27 AIDS 303 (2013).

In recent years, there has been a technological explosion in the ability to store and share the genetic data derived from biospecimens.[28] As a threshold matter, those working with genetic information no longer require access to the physical sample as the genetic data in the biospecimen can be sequenced, and the resulting genetic sequence data can be stored, electronically.[29] Today, the factor limiting the ability to store genetic data is no longer the size of the laboratory refrigerator, but instead the laboratory's data storage capacity, which, in the era of "cloud" storage, poses essentially no limit.[30] Similarly, sharing genetic data no longer requires mailing the physical specimen to its intended recipient. Instead, companies like Amazon and Google are facilitating the storage and sharing of genetic data using the "cloud" so as to make the data more accessible to scientists around the world.[31] Today, with the mere click of a mouse, an individual's genetic sequence can be uploaded to the cloud and shared with a potentially limitless number of people.[32]

Furthermore, at the time of the RAND report, the amount of information that could be learned from conducting genetic testing using biospecimens was extremely limited. The human genome had not yet been sequenced and genetic tests were available only for discrete genetic diseases such as Tay-Sachs and cystic fibrosis.[33] Today, in contrast, it is possible to discern an individual's entire genetic sequence from a single cell contained in a stored biospecimen[34]—and we do not yet know the

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28 *See* Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 8 (2006); Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 NEW ENG. J. MED. 793, 793 (2015) (noting that the prospect for precision medicine "has been dramatically improved by the recent development of large-scale biologic databases"); Lawrence O. Gostin et al., *Virus Sharing, Genetic Sequencing, and Global Health Security*, 345 SCI. 1295, 1296 (2014) (noting that genetic sequencing technologies "fundamentally change the paradigm").

29 *See* Gostin et al., *supra* note 28, at 1295 ("[P]harmaceutical researchers no longer require access to biological materials to develop products.").

30 That is not to say that data storage concerns about genetic sequences are trivial. In fact, scientists predict that genetic sequences "will soon take the lead as the biggest data beast in the world, eventually creating more digital information than astronomy, particle physics and even popular Internet sites like YouTube." Gebelhoff, *supra* note 25. In addition, the "amount of data being produced in genomics daily is doubling every seven months." *Id.*

31 *See id.*; Gostin et al., *supra* note 28, at 1296 (noting the "potential for broad global dissemination").

32 *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53938 (Sept. 8, 2015) ("The sheer volume of data that can be generated in research, the ease with which it can be shared, and the ways in which it can be used to identify individuals were simply not possible, or even imaginable, when the Common Rule was first adopted.").

33 *See, e.g.*, Vicki Brower, *FDA to Regulate Direct-to-Consumer Genetic Tests*, 102 J. NAT'L CANCER INST. 1610, 1610 (2010).

34 *See, e.g.*, PRIVACY AND PROGRESS, *supra* note 5, at 17.

limits of what an individual's genetic sequence can reveal.[35] As of April 2012, there were genetic tests for over 2,600 disease-causing variants.[36] This represents a mere fraction of the possible variants in our three-billion-base-pair long genetic sequence.[37] Accordingly, there are millions—perhaps even billions—of genetic variants for which the meaning and importance is not yet understood.[38]

C. *The Potential Backlash to the Nonconsensual Collection and Use of Genetic Data*

Genetic information is unique to individuals, intrinsically connected to identity, and has the potential to reveal sensitive health information about individuals and their biologically-linked family members.[39] Widespread recognition of the surreptitious, nonconsensual mass collection of genetic data has the potential to generate societal backlash that could halt important biomedical progress.[40]

Backlash against the nonconsensual mass collection, storage, and use of genetic data has, in fact, already occurred, albeit only at the state level. In two states, Texas and Minnesota, parents filed lawsuits after learning that blood samples collected without consent from their newborn children as part of a public health screening were stored, and subsequently used, without consent for unrelated purposes.[41] In Texas, the lawsuit *Beleno v. Texas Department of Health Services*[42] considered Texas's policy of collecting newborn blood samples and storing them "indefinitely . . . for purposes of undisclosed research unrelated to the

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35 *See, e.g.*, Catherine Gliwa & Benjamin E. Berkman, *Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?*, 13 AM. J. OF BIOETHICS 32, 36 (2013) ("Genomic science is still in its infancy, and the amount we know about the relationship between genomic data and human disease is dwarfed by the amount we do not yet know.").

36 *See* Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD & DRUG L.J. 475, 480 (2012) ("As of April 2012, genetic tests were available for 2,612 diseases . . . .").

37 *See, e.g.*, PRIVACY AND PROGRESS, *supra* note 5, at 110.

38 *See* Greer Donley, Sara Chandros Hull & Benjamin E. Berkman, *Prenatal Whole Genome Sequencing: Just Because We Can, Should We?*, 42 HASTINGS CTR. REP. 28, 32 (2012).

39 *See* Bregman-Eschet, *supra* note 28, at 7; Paul J. van Diest & Julian Savulescu, *For and Against: No Consent Should Be Needed for Using Leftover Body Material for Scientific Purposes*, 325 BRITISH MED. J. 648, 649 (2002).

40 *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53944 (Sept. 8, 2015) ("[C]ontinuing to allow secondary research with biospecimens collected without consent for research places the publicly-funded research enterprise in an increasingly untenable position because it is not consistent with the majority of the public's wishes, which reflect legitimate autonomy interests.").

41 Bearder v. Minnesota, 806 N.W.2d 766, 776 (Minn. 2011); Complaint at 4–5, Beleno v. Tex. Dep't of State Health Servs., No. SA-09-CA-0188-FB (W.D. Tex. Mar. 12, 2009).

42 *Id.*

purposes for which the infants' blood was originally drawn, without the knowledge or consent of the infants' parents."[43] The lawsuit ultimately settled out of court with the Texas Department of Health Services agreeing to incinerate approximately 5.3 million newborn blood samples that had been collected and to modify the collection procedures going forward.[44]

On March 11, 2009, Minnesota parents brought a similar lawsuit, *Bearder v. Minnesota*,[45] alleging "that the state's dissemination and use of [newborn blood samples] for research without obtaining written informed consent"[46] violated a state law stating that "genetic information . . . may be collected by a government entity . . . only with the written informed consent of the individual."[47] The court ruled in favor of the plaintiffs holding that the collection, sharing, and use of the newborn blood samples violated the privacy statute.[48] The Minnesota Health Department ultimately "agreed to follow a November 2011 Minnesota Supreme Court order to destroy all blood samples in long-term storage . . . and to pay nearly $1 million in legal costs."[49]

The resounding message of these lawsuits is one of loss—the parents' loss of trust in state public health departments;[50] the loss of

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43 Albert R. Serrano IV, *Pieces of Me: The Immoral and Unjust Appropriation of Genetic Material*, 16 MICH. ST. J. MED. & L. 95, 110–11 (2011).

44 *Id.*; Ann Waldo, *The Texas Newborn Bloodspot Saga Has Reached a Sad—and Preventable—Conclusion*, GENOMICS L. REP. (Mar. 16, 2010), http://www.genomicslawreport.com/index.php/2010/03/16/the-texas-newborn-bloodspot-saga-has-reached-a-sad-and-preventable-conclusion. While the case was ongoing, the Texas state government passed new legislation pertaining to newborn blood screening. *See* Sandra J. Carnahan, *Biobanking Newborn Bloodspots for Genetic Research Without Consent*, 14 J. HEALTH CARE L. & POL'Y 299, 309 (2011). The legislation implemented an opt out, or presumed consent, model which requires the attending physician to explain the state's system of retaining and storing the bloodspots and permitting future research use of de-identified samples, and to provide the patient with a form that can be used to opt out of the state retaining the newborn's genetic material. *Id.* at 308–09. Physicians are not, however, required to explain the parent's options, nor are they required to return forms to the state. *Id.*

45 806 N.W.2d at 776.

46 Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 MINN. J.L. SCI. & TECH. 729, 733 (2014) [hereinafter Suter, *Newborn Screening*].

47 Plaintiff's Memorandum of Law at 1–2, 6–7, 17, Bearder v. Minnesota, No. 27 CV 09-5615 (D. Minn. Oct. 1, 2009), 2009 WL 5427609 (quoting Minn. Stat. Ann. § 13.386 (West 2013)); *see also* Proposed Amendments to Rules Governing Newborn Screening, Minnesota Rules, Ch. 4615, 19–21, No. 11-0900-17586-1 (proposed Jan. 23, 2007).

48 *Bearder*, 806 N.W.2d at 776.

49 Jeremy Olson, *Minnesota Must Destroy 1 Million Newborn Blood Samples*, STAR TRIB. (Jan. 14, 2014, 12:57 AM), http://www.startribune.com/minnesota-must-destroy-1-million-newborn-blood-samples/239952831.

50 Mary Ann Roser, *State Agrees to Destroy More than 5 Million Stored Blood Samples from Newborns*, STATESMAN (Dec. 23, 2009, 5:25 AM), http://www.statesman.com/news/news/state-regional/state-agrees-to-destroy-more-than-5-million-stored/nRZK9.

time and energy battling in court; and the loss of millions of genetic samples—samples that, as discussed in Section III.B, are particularly valuable. Lost, too, were voices that could have advocated for a more temperate response than the incineration of millions of samples:

> Neither parents who would have wanted their children's bloodspots to be saved and used in research, nor countless parents who are eagerly waiting for the discovery of tests and treatments for their children's conditions, had any voice whatsoever in the litigation or the public policy decision-making. Likewise, researchers who could have defended the tremendous medical benefits expected from their research played no part. Decisions were made under pressure and stress that simply did not reflect a broad spectrum of society's interests.[51]

There are, however, valuable lessons to be learned, primarily about the importance of trust. Public trust is essential to biomedical research and to biobanks that store genetic data. Without trust, individuals may be less willing to contribute their genetic material.[52] Data shows that people are remarkably willing to contribute their genetic data to biobanks if asked beforehand.[53] Even Andrea Beleno, the named plaintiff in the Texas lawsuit, might have consented to the collection, storage, sharing, and subsequent use of her newborn's genetic data had she had trust in the enterprise: Beleno stated, "If they had asked me . . . I probably would have consented. The fact that it was a secret program really made me so suspicious of the true motives, there's no way I would consent now."[54]

The choices that we, as a society, make about the collection and use of genetic material have consequences. Done poorly—without trust and without consent—the collection and use of genetic material can lead to lawsuits and incineration of samples. Done well, the collection and use of genetic material offer potentially limitless societal benefits.

II. THE COLLECTION OF GENETIC MATERIAL FOR SUBSEQUENT NONCONSENSUAL USE

There is little we can do to prevent the regular and routine shedding of genetic material. As one scholar argues, "Everywhere we go . . . we leave behind a trail of genetic evidence: cells that are naturally

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51 Waldo, *supra* note 44.

52 *See* Javitt, *supra* note 22, at 748.

53 *See* Taralyn Tan, *Newborns' DNA: Don't Deny Scientists this Useful Resource*, BIOPERSPECTIVES (Apr. 13, 2010), http://www.genengnews.com/gen-articles/newborns-dna-don-t-deny-scientists-this-useful-resource/4377; *see also infra* Section V.C.

54 Roser, *supra* note 50 (alteration in original) (quoting Andrea Beleno).

shed over time. Hair falls out, blood drips and cheek cells are gradually washed away by saliva, only to stick to the rim of a cup, utensil or drinking straw."[55] In most cases, these genetic remnants get swept up and thrown away without a second thought. In a range of encounters—including medical tests and procedures,[56] newborn screening,[57] direct-to-consumer genetic testing,[58] and encounters with the criminal justice system[59]—the surrendered genetic material is far more likely to be collected and stored without consent for subsequent use. This Part examines the encounters that are likely to result in the collection of genetic data.

A. *Medical Waste*

Every day, individuals walk into their doctors' offices seeking tests or procedures that require removal of blood or bodily tissue for additional analysis or to promote their health and wellbeing. In some instances, these tests and procedures are routine and may include blood draws or mole removals. Other times, the tests or procedures are more serious, including biopsies and appendectomies. Most patients give little thought to what becomes of their excised medical waste,[60] and many assume that the material is discarded after it has served its clinical purpose.[61] This assumption is often incorrect.

Medical waste is generated during clinical care when tests and medical procedures yield more blood or bodily tissue than is strictly necessary for diagnosis or treatment.[62] When the subsequent testing is

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55 Rachel Ross, *A Trail of Genetic Evidence Follows Us All,* TORONTO STAR, Feb. 2, 2004, at D03.

56 *See infra* Section II.A.

57 *See infra* Section II.B.

58 *See infra* Section II.C.

59 *See infra* Section II.D.

60 *See* Dunn, *supra* note 26, at 636 ("When these biospecimens are extracted, most patients do not think twice about what happens to these cells beyond the diagnostic or therapeutic use for one's own illness or affliction.").

61 The reality is that few patients understand what happens to medical samples that have filled their therapeutic or diagnostic purpose. For example, in a survey of Department of Veterans Affairs (VA) patients, when asked what they "assume happens to leftover blood or tissue from a VA hospital visit," forty-seven percent "were unsure," forty-nine percent assumed that the leftover samples "[were] discarded," and four percent assumed they were "being stored or used for research." David Kaufman et al., *Preferences for Opt-in and Opt-out Enrollment and Consent Models in Biobank Research: A National Survey of Veterans Administration Patients*, 14 GENETICS IN MED. 787, 788–89 (2012).

62 *See* van Diest & Savulescu, *supra* note 39, at 648. The term "medical waste" is an umbrella term that makes reference to a number of components. Under the Medical Waste Tracking Act of 1988, the definition of medical waste includes "[p]athological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy," and "[w]aste

complete and the excised material is no longer of therapeutic value to the patient, the question then becomes whether to discard the sample or instead to retain it for future use.[63] Both options—storing and discarding the samples—are considered routine.[64] Discarding samples saves costs and space, but stored samples are valuable resources.[65] The decision to store or discard is not generally made by the patient; in fact, the patient is unlikely to know that the decision was ever even made.[66]

Perhaps the most famous example of the nonconsensual collection of medical waste involves Henrietta Lacks. As described by Rebecca Skloot in the New York Times bestseller *The Immortal Life of Henrietta Lacks*, cells taken from Henrietta Lacks's body as part of routine clinical care for cervical cancer were transferred to a researcher who was trying to keep cells alive in culture indefinitely.[67] Without Henrietta Lacks's knowledge or consent, her excised cervical cancer cells became the first "immortal" cell line, able to replicate indefinitely when stored under proper conditions.[68] Even today, Henrietta Lacks's cell line is the most frequently used in the world.[69]

Henrietta Lacks is far from alone in having her excised medical waste collected and stored for subsequent use. Today, discarded medical waste samples form the "vast majority" of the biospecimens that are collected and stored without consent for subsequent nonconsensual

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human blood and products of blood, including serum, plasma, and other blood components." 42 U.S.C. § 6992a(a)(2)–(a)(3) (2012). Blood and excised bodily tissues have also been termed "residues from medical procedures," "surplus materials," "body waste," "excess clinical materials," and "redundant tissue." Eugenijus Gefenas et al., *Turning Residual Human Biological Materials into Research Collections: Playing with Consent*, 38 J. MED. ETHICS 351, 352 (2012).

63 *See, e.g.*, Jean McHale, *Waste, Ownership and Bodily Products*, 8 HEALTH CARE ANALYSIS 123, 123 (2000); van Diest & Savulescu, *supra* note 39, at 648; E. Vermeulen et al., *A Trial of Consent Procedures for Future Research with Clinically Derived Biological Samples*, 101 BRITISH J. CANCER 1505, 1505 (2009).

64 *See* McHale, *supra* note 63, at 123–24.

65 *See* van Diest & Savulescu, *supra* note 39, at 648; Vermeulen et al., *supra* note 63, at 1505.

66 *See, e.g.*, Maryjoy Ballantyne, Note, *One Man's Trash Is Another Man's Treasure: Increasing Patient Autonomy Through a Limited Self-Intellectual Property Right*, 3 GEO. J.L. & PUB. POL'Y 567, 582 (2005) (noting that obtaining tissue in the clinic only requires "that informed consent be obtained for the physical risks involved in the removal of the tissue").

67 *See* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS 33 (2010).

68 *Id.* at 30.

69 *Id.* at 13–83; *see also* Francis Collins, *HeLa Cells: A New Chapter in an Enduring Story*, NIH DIRECTOR'S BLOG (Aug. 7, 2013), https://directorsblog.nih.gov/2013/08/07/hela-cells-a-new-chapter-in-an-enduring-story ("While other immortalized lines are now available, HeLa remains the most widely used cell line in biomedical research. In fact, they are referred to in more than 74,000 scientific publications."); Denise Watson, *Cancer Cells Killed Henrietta Lacks—Then Made Her Immortal*, VIRGINIAN-PILOT (May 10, 2010), http://pilotonline.com/news/local/health/cancer-cells-killed-henrietta-lacks---then-made-her/article_17bd351a-f606-54fb-a499-b6a84cb3a286.html.

use.[70] Per the RAND report, as of 1999, pathology samples—a subset of the larger total number of samples—had already been retained from 160 million individuals, with samples from an estimated additional eight million individuals accessioned each year.[71] At that rate, pathology samples from an additional 120 million people would have been accessioned as of today—accounting for approximately eighty-eight percent of the American population.[72]

The primary justification for the collection of genetic data for a range of subsequent nonconsensual uses is that the material has been abandoned. In *Venner v. Maryland*, a criminal case considering ongoing interests in medical waste, a Maryland court stated, "When one places, or permits others to place waste material from his body into the stream of ultimate disposition as waste, he has abandoned whatever legal right he theretofore had to protect it from prying eyes or acquisitive hands."[73] The same holding was reached in *Moore v. Regents*, a seminal case considering ownership interests in excised medical waste.[74] In *Moore*, the Supreme Court of California ultimately concluded that individuals "abandon [their] bodily material when [they] consent to its removal and make no provision for its disposition or return"—essentially the legal standard of abandonment.[75] Thus, as others have concluded, "waste material is sure to be considered abandoned property."[76]

The collection of millions of excised pathological samples and medical waste has generated a need to store these samples to facilitate subsequent access and use. Given the potential windfall that can come to institutions that make important biomedical discoveries, institutions around the country are "in an arms race to amass databases of genetic information that weave together genetic, sensor, lifestyle, environmental, microbiome and medical-record data."[77] Institutions across the country—such as "Vanderbilt University Medical Center, the

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70 *See RAND Report*, *supra* note 20, at D-40.

71 *See id.* at D-39.

72 This calculation uses the estimated number of individuals included in the samples, 280 million, and the estimated U.S. population as of 2014. *See State & County QuickFacts*, U.S. CENSUS BUREAU, http://quickfacts.census.gov/qfd/states/00000.html (last visited Aug. 10, 2015).

73 Venner v. State, 354 A.2d 483, 499 (Md. Ct. Spec. App. 1976).

74 Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 489–90 (Cal. 1990).

75 Meredith M. Render, *The Law of the Body*, 62 EMORY L.J. 549, 572–73 (2013).

76 Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 172 (2009) [hereinafter Ram, *Assigning Rights*].

77 Daniela Hernandez, *Big Tech Has Your Email and Photos. Now It's on a Quest to Own Your DNA*, HUFFINGTON POST (July 20, 2015, 8:31 AM), http://www.huffingtonpost.com/entry/big-tech-dna_us_55ac3376e4b0d2ded39f46eb.

Marshfield Clinic, and Northwestern University"[78]—comprising a variety of organizational structures, including academic institutions, hospital-industry partnerships, industry entities, for-profit repositories, patient-led initiatives, and public-private partnerships,[79] have developed extensive biobanks for excised medical waste. As one example, Kaiser Permanente, the country's largest nonprofit healthcare provider, is developing a biobank "where adult members would be asked to contribute an additional tube of blood during a routine blood draw," and hopes to enroll at least 500,000 individuals.[80]

Minor limitations on the ability to collect and store excised medical waste arise from HIPAA's Privacy Rule and the Common Rule, the federal regulations governing federally supported biomedical research.[81] These laws primarily limit the extent to which biospecimens can be stored with identifiers.[82] Under the Privacy Rule, biospecimens that are stored without eighteen specified identifiers (including name, address, birth date, and social security number)[83] are subject to "no restrictions on [their] use or disclosure."[84] Accordingly, practitioners can collect, store, share, and use de-identified biospecimens without limitation.

Biospecimens stored with specified identifiers can be used or disclosed without the source's authorization under a series of

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78 Dunn, *supra* note 26, at 642–43 (footnotes omitted).

79 *See, e.g.*, Jennifer S. Geetter, *Another Man's Treasure: The Promise and Pitfalls of Leveraging Existing Biomedical Assets for Future Use*, J. HEALTH & LIFE SCI. L., June 2011, at 1, 2.

80 Alanna Kulchak Rahm et al., *Biobanking for Research: A Survey of Patient Population Attitudes and Understanding*, 4 J. COMMUNITY GENETICS 445, 445–46 (2013); *see also* Erika Check Hayden, *Major Biobank Launches in America*, NATURE (Dec. 17, 2008), http://www.nature.com/news/2008/081217/full/news.2008.1315.html; Jocelyn Kaiser, *Largest U.S. Genetic Biobank Reveals Early Findings*, SCI. (Nov. 9, 2012, 3:04 PM), http://news.sciencemag.org/2012/11/largest-u.s.-genetic-biobank-reveals-early-findings.

81 HIPAA Privacy Rule, 45 C.F.R. pts. 160, 164 (2007). The parallel FDA regulations that apply to research are similarly unlikely to limit the collection of data both because the parameters are fairly similar to those of the Common Rule, and because the FDA regulations only govern "trials relied upon to determine and establish a product's safety and efficacy" and do not apply to "studies necessary for obtaining patent protections, Phase IV trials, or generally, where the company and/or sponsor are seeking to identify genetic predispositions to traits or illnesses but are not seeking to create a drug or device that would require FDA approval." Valerie Gutmann Koch, *PGTandMe: Social Networking-Based Genetic Testing and the Evolving Research Model*, 22 HEALTH MATRIX 33, 61–62 (2012). For more information, see Section III.B.

82 HIPAA's Privacy Rule, intended to "assure that individuals' health information is properly protected," applies to "covered entities"—a term of art that includes health care providers, hospitals, physicians, dentists, and other practitioners. U.S. DEP'T HEALTH & HUMAN SERVS., OCR PRIVACY BRIEF: SUMMARY OF THE HIPAA PRIVACY RULE 1–3 (2003) [hereinafter OCR PRIVACY BRIEF—HIPAA], http://www.helpingyoucare.com/wp-content/uploads/2010/10/Summary-of-the-HIPAA-Privacy-Rule-Office-For-Civil-Rights-Privacy-Brief.pdf.

83 *Id.* at 3–4, 4 n.15.

84 *Id.* at 4.

exceptions, two of which might authorize nonconsensual use or disclosure of biospecimens. First, the information can be released as part of a "Limited Data Set"—a set for which some, but not all, of specified identifiers are removed, and for which the intended recipient is expected to implement specific informational safeguards.[85] Second, information can be released if an institutional review board (IRB) has waived the requirement that individuals provide informed consent for research.[86] An IRB may waive the requirement of informed consent at the collection, permitting subsequent nonconsensual disclosure and use under the HIPAA exception, if: "(1) The research involves no more than minimal risk to subjects; (2) The waiver or alternation [does] not adversely affect the rights and welfare of subjects; (3) The research could not . . . be carried out without the waiver or alteration; and, (4) Whenever appropriate, the subjects [are] provided with additional pertinent information after participation."[87] These requirements are often considered to be satisfied in research using genetic data because the large numbers of samples are generally thought to make consent impracticable and, given that no additional intervention is being conducted, the risks of research are thought to be minimal.[88] Accordingly, the nonconsensual collection, storage, and disclosure of even identifiable medical waste are not significantly constrained by legal restrictions.

B. *Newborn Screening*

Each year, blood samples from almost four million newborns are collected, stored, and subsequently sent to a laboratory where they are screened for a range of possible conditions.[89] The purpose of this public

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85 45 C.F.R. § 164.514(e) (2016).

86 *Id.* § 164.512(i)(1)(i); *see also Institutional Review Boards Frequently Asked Questions—Information Sheet*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm (last updated Jan. 25, 2016) ("[A]n IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.").

87 45 C.F.R. § 46.116(d).

88 *See, e.g.*, Geetter, *supra* note 79, at 72–73.

89 *See* Carnahan, *supra* note 44, at 301; Nanette Elster, *Human Genetic Sampling: Ethical, Legal, and Social Considerations, Future Uses of Residual Newborn Blood Spots: Legal and Ethical Considerations*, 45 JURIMETRICS J. 179, 181 (2005). The list of possible illnesses varies by state. *See* Carnahan, *supra* note 44, at 302.

health measure is to discover affected children before they become symptomatic, with the associated health benefits that come with early detection.[90] Given the benefits of newborn screening—both to individuals' and the public's health—all fifty states currently mandate newborn screening.[91]

Newborn bloodspots containing the infant's entire genetic sequence are generally retained after collection both for public health purposes (e.g., to permit retesting as needed) and, in some cases, for subsequent use.[92] A recent study noted that twelve states retain stored newborn samples without a stated justification.[93] Twelve states retain samples for twenty-one years or longer,[94] and seven states retain samples indefinitely.[95] Newborn blood spots are generally stored with identifying information—information that might include the mother's name, the hospital where the child was born, and the child's date of birth.[96] A recent study found that "all except two of the 36 state . . . programs studied stored their newborn bloodspots with the identifying information present."[97]

For the most part, newborn screening is conducted without parental consent.[98] Only two jurisdictions—the District of Columbia and Wyoming—affirmatively require parental consent.[99] Even where required, it is hard to obtain meaningful consent given that testing is conducted within the first days of a newborn's life[100]—a time when much is in flux. As a result, most parents are unaware that their newborn's blood is collected for this public health screening program,[101] and even fewer are aware that the samples from their newborns are

90 *See* Carnahan, *supra* note 44, at 301–02.

91 *See id.* at 302.

92 *See id.* at 304.

93 *See* Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 271 (2002).

94 *See* Scutti, *supra* note 18 .

95 *See* CITIZENS' COUNCIL ON HEALTH CARE, STATE BY STATE GOVERNMENT NEWBORN BLOOD & BABY DNA RETENTION PRACTICES 1–2 (2009), http://www.cchfreedom.org/pr/50_States-Newborn_Blood_Retention_Policies_FINAL.pdf.

96 Carnahan, *supra* note 44, at 301.

97 *Id.* at 320.

98 *See* U.S. GEN. ACCOUNTING OFFICE, GAO-03-449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS 22 (2003). The justification for nonconsensual testing is the state's police power to promote public welfare. *See* Carnahan, *supra* note 44, at 304; Suter, *Newborn Screening*, *supra* note 46, at 750 ("The mandatory nature of NBS has been justified by these police powers because NBS is touted as a public health effort.").

99 *See* D.C. CODE §§ 7-831 to -840 (2016); WYO. STAT. ANN. §§ 35-4-801 to -802 (2016).

100 *See, e.g.*, Carnahan, *supra* note 44, at 302 ("Newborn babies have been screened shortly after birth for over forty years.").

101 *See* Suter, *Newborn Screening*, *supra* note 46, at 730–31 ("[T]he majority of parents do not realize that in every state, a small blood sample is collected from newborns to test for inborn errors of metabolism (many of which are inherited)."); *see also* Tan, *supra* note 53.

being retained "for long periods or indefinitely, with few, if any, limits on third-party access to and uses of these samples."[102] Accordingly, even in the rare instances when parents provide meaningful informed consent for the public health screening, they may nevertheless be unaware of the long-term storage of their newborn's genetic data.

An astonishing number of samples of newborn genetic material have been stored for subsequent use in the past fifteen years. The RAND report relied on survey data from 1994 finding that—using a "conservative estimate"—only 13.5 million newborn blood spots were stored.[103] Newborn blood screening lawsuits have provided additional insight into the recent increase in the number of stored samples. For example, Texas did not start collecting newborn blood samples until 2002, but had a collection of 5.3 million samples by 2009.[104] Given that blood samples from almost four million newborns are collected annually,[105] an additional eighty million samples could have been collected and stored in the twenty years since the national survey was conducted on which the RAND report relied, for a total of approximately 100 million samples.

The justification for the nonconsensual collection and storage of newborn blood spots and the genetic data that they contain is different from the justification for the nonconsensual collection of excised medical waste. The justification is not that the samples have been abandoned, as was the case with medical waste. Although a case could be made that parents made no provision for the disposition or return of the newborn's blood sample—the reasoning set forth in *Moore*—the requirement would be somewhat strained given that most parents are unaware of, and have not consented to, the original testing. Rather, the justification seems to be that the newborn blood samples are extremely useful.[106] Newborn blood spots "are an especially rich source of research material: they are stable over time, they constitute an unbiased collection of samples since they represent the entire population, and they can potentially be linked to basic demographic information."[107] Population-wide genetic databases culled from newborn blood spots can help assess the prevalence of gene variants across populations,[108] and can help study "factors such as the mother's health and in utero

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102 Suter, *Newborn Screening*, *supra* note 46, at 730–31.

103 *RAND Report*, *supra* note 20, at D-29–30.

104 Carnahan, *supra* note 44, at 305 n.40.

105 *Id.* at 301.

106 *See, e.g.*, *infra* notes 107–09 and accompanying text.

107 Suter, *Newborn Screening*, *supra* note 46, at 756.

108 *See* Elster, *supra* note 89, at 184 ("DBS may provide useful data on the prevalence of gene variants that can affect public health, the relationship between these variants and disease . . . .").

environment in relation to rare disorders"[109]—information that is harder to assess when people self-select into databases in ways that result in skewed and unrepresentative samples.

Accordingly, genetic samples are collected from millions of newborns each year as part of a public health screening program. For reasons of utility, these genetic samples are stored for subsequent use without the knowledge or consent of the parents involved.

C. *Direct-to-Consumer Genetic Testing*

Since the launch of the direct-to-consumer (DTC) genetic testing industry in 2007,[110] consumers have proven willing to provide their genetic material in exchange for information about themselves. DTC genetic testing companies typically advertise and operate online, and consumers order tests online, receive sample collection kits, submit cheek swabs or saliva samples, and then await the results.[111] The genetic results returned through November 2013—when return of health results was halted as the FDA considered how best to regulate DTC genetic testing[112]—ranged from the mundane, such as excessive earwax, to the serious, including the likelihood of developing diseases such as breast cancer or Alzheimer's disease.[113] In June 2015, 23andMe—one of the leading providers of DTC genetic testing—provided services to its one-millionth customer.[114] AncestryDNA, another market leader, has also acquired more than one million consumers.[115]

A key part of these companies' business models is the ability to collect, store, and share consumers' genetic data. As Valerie Gutmann Koch observed, the business models of these companies "do not focus on profits from the sale of genetic tests, but from gathering the genetic and personal data that can be licensed and sold to institutions, academic

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109 Tan, *supra* note 53.

110 *See* Kayte Spector-Bagdady & Elizabeth Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677 (2014).

111 *Id.* at 689.

112 *Id.* at 698, 703–04.

113 *Id.* at 689.

114 Lydia Ramsey, *23andMe CEO Defends Practice of Sharing Genetic Info with Pharma Companies*, BUS. INSIDER (July 7, 2015, 12:48 PM), http://www.businessinsider.com/23andme-anne-wojcicki-marketplace-interview-2015-7 ("[This is] more than double the amount of users the company had in November 2013, when the FDA put a hold on releasing health reports to customers.").

115 Katie M. Palmer, *Another Personal Genetics Company Is Sharing Client Data*, WIRED (July 21, 2015, 9:00 AM), http://www.wired.com/2015/07/another-personal-genetics-company-selling-client-data.

researchers, or drug companies."[116] In many ways, the surprising thing is that these DTC genetic testing companies have "convinced customers to pay to give their genetic data away, at a cost of about $100 per sample."[117]

But these DTC genetic testing companies have, in fact, managed to successfully convince consumers to share their genetic data. A reported ninety percent of AncestryDNA users have agreed that the company can share "their anonymized data for research purposes—whether that research is being conducted by a for-profit company or a nonprofit academic institution."[118] In the case of 23andMe, approximately eighty percent of its customers permit their identifiable data to be shared with third parties, including pharmaceutical companies.[119] Not only are 23andMe consumers willing to have their data shared, a large number of the more than eighty percent of 23andMe consumers who have opted into research have actively answered survey questions about their health status, environment, and lifestyle to supplement the genetic data so as to be of more use to researchers.[120]

The justification for collecting and sharing this genetic data is that consumers have consented to their data being shared. 23andMe, for example, seeks consent from consumers before using consumers' identifiable data in research.[121] There are, however, questions about the thoroughness of the informed consent process. Consumers who choose to enroll in research likely never "interact personally with anyone, let alone a medical professional."[122] In fact:

> [I]ndividuals may have been recruited, and have agreed to participate in hypothetical research, without any prior knowledge of how their genetic and phenotypic information will be used or who will be doing the research. Thus, they may already be "participating" in research (having submitted a biological sample and disclosed personal information and family history) before a protocol has been put in place.[123]

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116 Koch, *supra* note 81, at 50.

117 Palmer, *supra* note 115.

118 *Id.*

119 *See* Ramsey, *supra* note 114.

120 *See* Michael Grothaus, *How 23andMe Is Monetizing Your DNA*, FAST COMPANY (Jan. 5, 2015, 9:00 AM), http://www.fastcompany.com/3040356/what-23andme-is-doing-with-all-that-dna ("To date, more than 80% of our 800,000-plus customers have opted in to our research, and most answer survey questions." (quoting Angela Calman-Wonson)); *see also* Ramsey, *supra* note 114.

121 Koch, *supra* note 81, at 64; Angela L. Morrison, Note, *A Research Revolution: Genetic Testing Consumers Become Research (and Privacy) Guinea Pigs*, 9 J. ON TELECOMM. & HIGH TECH. L. 573, 586 (2011).

122 Morrison, *supra* note 121, at 592.

123 Koch, *supra* note 81, at 61.

These companies also retain the right to share de-identified data without consent.[124]

Through DTC genetic testing companies, millions of people have voluntarily agreed to give their genetic data away, with an extremely large percentage agreeing to let the DTC companies share their data with third parties.[125] This secondary sharing poses few, if any, limits on what third parties may do.[126]

D. *Criminal Justice and Abandoned DNA*

Genetic data enters law enforcement databases in a number of ways. Over the years, "[s]tate and federal laws have rapidly increased the list of qualifying crimes for entry into a DNA database."[127] Nearly every state requires the collection of DNA samples from convicted felons.[128] Forty-two states require the collection of genetic information from those convicted of at least some misdemeanors.[129] Thirty states collect DNA samples from individuals who were merely arrested but not convicted.[130] Local databases sometimes include genetic information about "victims, excluded suspects, or lab workers."[131]

In addition to the official collection channels, law enforcement officers often seek "abandoned" DNA.[132] DNA samples can be obtained from things left behind, including "bloodstains, semen stains, bones, teeth, hair, saliva, urine, feces, fingernail debris, muscle tissue, cigarette

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124 Morrison, *supra* note 122, at 585–86. The companies also take steps to de-identify the genetic data. The consent for AncestryDNA permits sharing of *anonymized* data, and 23andMe sets limits on when aggregated and self-reported information will be stripped of registration information and combined with data from other users. *Id.*; Palmer, *supra* note 115.

125 *See, e.g.*, *supra* notes 118–20 and accompanying text.

126 *See* Morrison, *supra* note 122, at 585–86 ("The company does not mention whether third parties with whom it shares information will be required to protect the confidentiality of that information or to refrain from attempts to reidentify individual contributors.").

127 Sasha E. Polonsky, Note, *"Banking" on Law Enforcement: Advocating a New Balancing Test for DNA Storage After* United States v. Kinkade, 83 WASH. U. L.Q. 1331, 1360 (2005).

128 *See* NAT'L CONFERENCE OF STATE LEGISLATURES, CONVICTED OFFENDERS REQUIRED TO SUBMIT DNA SAMPLES (2013), http://www.ncsl.org/Documents/cj/ConvictedOffendersDNALaws.pdf.

129 *Id.*

130 NAT'L CONFERENCE OF STATE LEGISLATURES, DNA ARRESTEE LAWS (2013), http://www.ncsl.org/Documents/cj/ArresteeDNALaws.pdf.

131 Natalie Ram, *Fortuity and Forensic Familial Identification*, 63 STAN. L. REV. 751, 762 (2011) [hereinafter Ram, *Fortuity*]. Although these profiles were not historically includable in the national database, "[u]nder recent amendments, states may now upload to NDIS any profile collected in a manner consistent with their own laws." *Id.* at 761.

132 Elizabeth E. Joh, *Reclaiming "Abandoned" DNA: The Fourth Amendment and Genetic Privacy*, 100 NW. U. L. REV. 857 (2006).

butts, postage stamps, dandruff, and, ironically, fingerprints."[133] Abandoned DNA used to obtain convictions has been found on cigarettes,[134] in wads of gum,[135] in spit on the floor,[136] and on discarded coffee cups.[137] In one particularly creative bit of police work, law enforcement officers reached out to a possible suspect in a cold case homicide, under the guise of a letter from a fictitious law firm, asking the suspect to join in a class action lawsuit about parking tickets.[138] After the suspect signed the form, put it in an envelope, licked the envelope shut, and mailed it, genetic material taken from the envelope flap implicated the suspect in the crime.[139] In considering the issue, the court found that the suspect abandoned his saliva by mailing the envelope.[140]

Genetic data is also shared through the Combined DNA Index System—generally known as CODIS—the generic term used to describe the FBI's criminal justice DNA databases.[141] CODIS contains profiles submitted by agencies in all fifty states, and by local participating forensic laboratories.[142] The goal of CODIS is to permit state and local law enforcement agencies to search genetic profiles that were lawfully acquired in other jurisdictions to assist in criminal investigations.[143] The national database contains over fourteen million profiles—nearly twelve million offender profiles, two million arrestee profiles, and over half a million forensic profiles[144]—and has been cited as having "added value" in over 270,000 investigations.[145]

The information stored and searchable at the national level is fairly limited. The most important piece of information is the DNA profile, which is limited to twenty-six numbers.[146] Each of the twenty-six numbers stands for the number of variant repeats at thirteen given

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133 Scherr, *supra* note 4, at 450–51 (citations omitted).

134 *See, e.g.*, Richard Willing, *Police Dupe Suspects into Giving up DNA*, USA TODAY, Sept. 11, 2003, at A3.

135 *See, e.g.*, Elizabeth M. Gillespie, *Need for Greed Ends with 'Cold Case' Arrest*, L.A. TIMES, June 1, 2003, at A20.

136 *See, e.g.*, Christopher Francescani, *Sex Fiend Admits He Killed 5 in Brooklyn*, N.Y. POST, Mar. 10, 2001, at 11.

137 *See, e.g.*, Jason Van Derbeken, *How Alleged Serial Killer Fell into Trap/Man's Loose Lips Led to Ruse to Get DNA*, S.F. CHRON., Sept. 21, 2003, at A1.

138 *See* Scherr, *supra* note 4, at 452.

139 *Id.* at 457.

140 State v. Athan, 158 P.3d 27, 33–34 (Wash. 2007) (en banc).

141 The databases were authorized by the DNA Identification Act of 1994. *See Frequently Asked Questions (FAQs) on the CODIS Program and the National DNA Index System*, FED. BUREAU INVESTIGATION, http://www.fbi.gov/about-us/lab/biometric-analysis/codis/codis-and-ndis-fact-sheet (last visited Aug. 10, 2015) [hereinafter *CODIS Fact Sheet*].

142 *Id.*

143 *See* Ram, *Fortuity*, *supra* note 131, at 760–61.

144 *CODIS-NDIS Statistics*, *supra* note 24.

145 *Id.*

146 *See* Ram, *Fortuity*, *supra* note 131, at 758; *see also CODIS Fact Sheet*, *supra* note 141.

genomic locations across the twenty-two nonsex chromosomes—there are two variants at each location, each inherited from one genetic parent.[147] Accordingly, instead of the string of As, Ts, Cs, and Gs generally thought to be a genetic profile, a genetic profile in CODIS consists of a string of numbers.[148] Identifiable information is, however, retained in state and local databases.[149]

One of the consequences of being included in criminal databases is the potential for being subject to "lifelong 'genetic surveillance'" through comparison to crime scene DNA.[150] This surveillance extends even to biologically-linked family members. Through a process of partial matching—releasing profiles that match some, but not all, of the profile numbers—investigators hope to stumble upon someone in the database who is closely related to the person of interest.[151] In a particularly colorful example, familial matching was used to crack the case of the Grim Sleeper killings—a series of murders spanning decades with a hiatus in killings lasting a dozen years.[152] Genetic material at the crime scenes was not an exact match of any of the profiles in CODIS, but was a partial match for several hundred people in California's state database.[153] Additional filtering led to one person who was a likely biological relative.[154] Police followed the new suspect, the father of the matching offender in the database, and, when the suspect threw out pizza, law enforcement officers were able to capture a sample of genetic material for testing.[155] The genetic material proved to be a match to genetic material left at the crime scenes.[156] The result is that inclusion in a criminal database subjects biologically-linked family members to lifelong enhanced genetic surveillance.

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147 For a more detailed explanation of the information stored, see Ram, *Fortuity*, *supra* note 131, at 760–61. CODIS profiles could also contain information about repeats on the Y chromosome—genetic markers inherited in full from father to son—or mitochondrial DNA, inherited exclusively from the mother. *Id.* at 758, 760.

148 The other information accessible at a national level is the identifier of the agency that submitted the DNA profile, a specimen identification number (assigned sequentially at the time of collection), and information about the DNA laboratory personnel associated with the analysis. *See CODIS Fact Sheet*, *supra* note 141. As a general rule, "[n]o names or other personal identifiers of the offenders, arrestees, or detainees are stored using the CODIS software." *Id.*

149 *See* Ram, *Fortuity*, *supra* note 131, at 761.

150 Kelly Lowenberg, *Applying the Fourth Amendment When DNA Collected for One Purpose Is Tested for Another*, 79 U. CIN. L. REV. 1289, 1317 (2011) (quoting Jeffrey Rosen, *Genetic Surveillance for All*, SLATE (Mar. 17, 2009), http://www.slate.com/id/2213958).

151 *See* Ram, *Fortuity, supra* note 131, at 753; *see also Familial Searching*, FED. BUREAU INVESTIGATION, https://www.fbi.gov/about-us/lab/biometric-analysis/codis/familial-searching (last visited Apr. 26, 2016).

152 Ram, *Fortuity*, *supra* note 131, at 753.

153 *Id.*

154 *Id.*

155 *Id.*

156 *Id.* at 754.

There are essentially no limits to law enforcement's ability to collect "abandoned" genetic material—not even the Fourth Amendment protections generally applicable to the collection of genetic material. For things "knowingly expose[d]" to public view,[157] individuals are considered not to retain a reasonable expectation of privacy such that the collection of abandoned genetic material is not limited by the Fourth Amendment.[158] The upshot, as articulated by Albert Scherr, is that:

> If a putative suspect . . . abandons his DNA in a public place, the police can do with the sample what they will, without limitation. The police can do the same for a suspect for whom they have only a hunch. They can also do the same for someone for whom they have no suspicion, including a victim or a witness. They can do so without a suspect's, a witness's, or a victim's consent or knowledge. If surreptitious DNA harvesting is not a "search" under the Fourth Amendment, the police can do whatever they want with anyone's DNA.[159]

Once a genetic sample is included in CODIS or the state and local databases, it is particularly challenging to have the record expunged. To request expungement of a DNA sample at the national level—the "complete removal of a DNA profile from the National DNA Index System and the destruction of the associated DNA sample[]"—an individual must provide "a certified copy of a final court order establishing that the conviction has been overturned" or "that such charge has been dismissed, has resulted in an acquittal, or that no charge was filed within the applicable time period."[160] At the state level, only thirty-eight states have statutes describing the process for getting a record expunged.[161] In all cases, expungement does not occur automatically after a reversal or dismissal; offenders are expected to initiate the procedure.[162] Accordingly, once collected and stored, this abandoned genetic material can implicate the individual or biologically-linked family members in criminal investigations across the country.

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157 Katz v. United States, 389 U.S. 347, 351 (1967).

158 *See* Scherr, *supra* note 4, at 454.

159 *Id.* at 449.

160 *CODIS-Expungement Policy*, FED. BUREAU INVESTIGATION, http://www.fbi.gov/about-us/lab/biometric-analysis/codis/codis_expungement (last visited Aug. 10, 2015).

161 *See* Mark A. Rothstein & Meghan K. Talbott, *The Expanding Use of DNA in Law Enforcement: What Role for Privacy?*, 34 J.L. MED. & ETHICS 153, 159 (2006).

162 *Id.* at 153.

III. NONCONSENSUAL USES OF GENETIC MATERIAL

Nearly every American has had their genetic material collected and stored without their knowledge or consent at some point during their lives.[163] This Part considers the primary uses for these collected samples—primarily research, commercialization, and criminal justice. Although the rules and regulatory structures for each of these uses differ, there are two major commonalities: first, there are few limits on the ability to use genetic data that has been collected without consent; and second, there is limited oversight when the nonconsensually collected data is used.

A. *Research*

The sheer number of excised medical waste samples collected means that this category provides much of the genetic material used in biomedical research.[164] As has been recognized, research protocols "frequently involve" the use of discarded medical waste.[165] The Common Rule Notice of Proposed Rulemaking noted that: "Because biospecimens and information that have been collected for clinical use or purposes other than for the proposed research are often an important source of information and material for investigators."[166]

Researchers also rely on genetic samples collected in other domains. In recent years, there has been an increase in the research use of newborn blood samples.[167] The use of newborn blood samples in research accelerated beginning in 2009 when the American College of Medical Genetics and Genomics received an NIH grant to develop a national newborn blood sample repository for use in research.[168] The

163 *See supra* Section II.A.

164 *See, e.g.*, *supra* notes 70–72 and accompanying text.

165 Stephanie Sgambati, *New Frontiers of Reprogenetics: SNP Profile Collection and Banking and the Resulting Duties in Medical Malpractice, Issues in Property Rights of Genetic Materials, and Liabilities in Genetic Privacy*, 27 SYRACUSE J. SCI. & TECH. L. 55, 74–75 (2012) (noting that research protocols "frequently involve the use of discard pathology specimens, which are all of the extra materials produced or removed during ordinary medical treatment that would typically be categorized as medical waste").

166 Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53969 (Sept. 8, 2015).

167 *See* Scutti, *supra* note 18 ("[I]ncreasingly, health departments are using—and sharing—the genetic information for research and analysis."); Suter, *Newborn Screening*, *supra* note 46, at 731 ("[E]vidence suggests that a great deal of research is being conducted on these stored blood spots by the state and other entities.").

168 Scutti, *supra* note 18.

repository currently makes three million, de-identified, HIPAA-compliant samples available to researchers.[169]

Use of collected samples in genetic research seems built into the mission of DTC genetic testing companies. As stated by Ann Wojcicki, the founder of 23andMe, "[t]he reason why we started this company was the research component."[170] 23andMe includes as one of its goals revolutionizing the way research is conducted.[171] 23andMe has "conducted research funded by the NIH and has collaborated with academic and industry partners."[172] 23andMe also conducts a fair amount of research in-house using the data that it collects from consumers.[173] In fact, 23andMe even has its own research arm—23andWe—that "investigat[es] the basic causes of disease [and] develop[s] drugs and other treatments."[174]

Criminal databases are also being made available for research, albeit to a much more limited extent.[175] Regulations governing CODIS limit use of de-identified samples to particular types of research, namely "identification research and protocol development."[176] Some states, however, permit wider use. For example, both Alabama[177] and Michigan[178] authorize use of their state law enforcement databases for medical research.[179] Researchers therefore rely on nonconsensually collected genetic data from a range of contexts.

Because of past research ethics abuses, both in the United States and abroad, biomedical research tends to be more highly regulated than

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169 *See Virtual Repository of Dried Blood Spots*, NEWBORN SCREENING TRANSLATIONAL RES. NETWORK, https://www.nbstrn.org/research-tools/virtual-repository-of-dried-blood-spots (last visited Aug. 10, 2015). Some states—including California, Iowa, Michigan, and New York—have also developed a repository that grants researchers access to genetic data from newborn blood samples for use in research. *See* Scutti, *supra* note 18.

170 Jessica Firger, *"Information is Empowering": 23andMe CEO on the Future of Genomics*, CBS NEWS (Apr. 6, 2015, 6:00 AM), http://www.cbsnews.com/news/23andme-ceo-anne-wojcicki-future-of-genomics.

171 *See* Koch, *supra* note 81, at 35.

172 Scutti, *supra* note 18.

173 *See* Koch, *supra* note 81, at 41; *see also Research*, 23ANDME, https://www.23andme.com/research (last visited Apr. 26, 2016).

174 Morrison, *supra* note 122, at 580–81. In June 2010, investigators at 23andMe published a genome-wide association study using data 23andMe consumers provided. *See* Koch, *supra* note 81, at 43.

175 Despite concerns that criminal databases will someday be used by researchers "to predict the likelihood that a given individual will engage in certain types of criminal, or non-criminal but perhaps socially disfavored, behavior," such research has not yet come to pass. Scherr, *supra* note 4, at 493.

176 *CODIS Fact Sheet*, *supra* note 141.

177 ALA. CODE § 36-18-31 (2016).

178 MICH. COMP. LAWS ANN. § 28.176(d) (West 2015).

179 As of 2006, only eight states explicitly prohibited such use, whereas forty states were silent on the matter. *See* Rothstein & Talbott, *supra* note 161, at 159.

comparable activities.[180] In the United States, the "Basic HHS Policy for the Protection of Human Research Subjects" (known as the "Common Rule") is the regulation that governs federally funded research.[181] The Common Rule "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency,"[182] but does not generally govern research carried out by private actors like DTC genetic testing companies or pharmaceutical companies.[183]

As a general rule, the Common Rule requires that "no investigator . . . involve a human being as a subject in research . . . unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."[184] To effectuate the Common Rule's aim of "meaningfully add[ing] to the protection of the rights and welfare of the subjects,"[185] the Common Rule puts in place a system of prior review by an IRB.[186] The IRB is tasked with, among other things, ensuring that risks to subjects are minimized and reasonable in relation to the anticipated benefits, participants are selected equitably, and informed consent is administered properly.[187]

Although it is currently undergoing revision, as presently implemented, the Common Rule does away with the participant protections of informed consent and prior IRB review in many cases in which research involves the use of already collected biospecimens. First, if research uses biospecimens that are de-identified,[188] the research is not considered human subjects research at all, and the Common Rule

180 *See, e.g.*, PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, ANTICIPATE AND COMMUNICATE: ETHICAL MANAGEMENT OF INCIDENTAL AND SECONDARY FINDINGS IN THE CLINICAL, RESEARCH, AND DIRECT-TO-CONSUMER CONTEXTS 98–100 (2013) (noting the extent to which direct-to-consumer genetic testing is comparatively less regulated).

181 *See* Basic HHS Policy for Protection of Human Research Subject, 45 C.F.R. subtit. A, subch. A, pt. 46, subpt. A (2015); *see also Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVICES, http://www.hhs.gov/ohrp/humansubjects/commonrule (last updated Mar. 18, 2016).

182 45 C.F.R. § 46.101(a).

183 *See id.* The parallel FDA regulations could also apply if research is being conducted to "determine and establish a product's safety and efficacy." Koch, *supra* note 81, at 61.

184 45 C.F.R. § 46.116.

185 *Id.* § 46.109(b).

186 *Id.* § 46.109.

187 *Id.* § 46.111.

188 Under the Common Rule, the concern is about information for which "the identity of the subject is or may readily be ascertained by the investigator." *Id.* § 46.102(f).

does not apply.[189] Thus, researchers using de-identified genetic data are not obligated to obtain consent for use or third-party review.

Second, even if the research uses identifiable biospecimens such that it *is* considered human subjects research, the research may nevertheless be exempt from the Common Rule requirements of informed consent and IRB review. To qualify as exempt, research using existing genetic data—such as the data stored in biobanks—must be "recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."[190] A researcher who receives identifiable biospecimens is not required to obtain consent or seek third-party review for research so long as information about the samples is recorded in a de-identified manner.[191]

Third, even if the research is not considered exempt—perhaps because the researcher who receives identifiable samples wishes to record the information with identifiers—the requirements for informed consent might nevertheless be *waived* by an IRB.[192] Research using identifiable biospecimens qualifies for a waiver in circumstances where

> obtaining informed consent is impracticable, for example, because of the sheer volume of people contributing data and/or biological materials to the initiative or because the data or biological materials were provided in the past . . . and the hospital or other entity seeking to establish the repository or use the biomedical assets for future use cannot locate and contact these individuals.[193]

Recent legal modifications, however, have shifted the analysis when it comes to use of newborn blood samples in research. Until recently, the use of newborn blood samples in research was not subject to the requirements of the Common Rule and, therefore, did not require informed consent or prior IRB review.[194] This changed somewhat on

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189 *Id.* ("Human subject means a living individual about whom an investigator . . . conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.").

190 *Id.* § 46.101(b)(4).

191 *Id.*

192 *Id.* § 46.116(d). There are four prerequisites to such a waiver:

> (1) The research involves no more than minimal risk to the subjects; (2) The waiver . . . will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver . . . ; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Id.

193 Geetter, *supra* note 79, at 73.

194 *See* Carnahan, *supra* note 44, at 315–16; Suter, *Newborn Screening*, *supra* note 46, at 760 (noting that "state NBS programs have 'not traditionally been viewed as subject' to the Common Rule given that they are regulated by state health departments" (quoting Carnahan, *supra* note 44, at 315–16)).

December 18, 2014 when President Obama signed the "Newborn Screening Saves Lives Reauthorization Act of 2014" into law.[195] The Act, passed in the wake of high profile lawsuits concerning the nonconsensual use of newborn blood samples,[196] deems research using newborn blood samples to be human subjects research under the Common Rule, and it prohibits waiver of the informed consent requirements.[197] The Act, however, only applies to samples collected following the Act's enactment,[198] which leaves newborn blood samples collected prior to enactment available for research use without compliance with the Common Rule.

Recent proposed modifications to the Common Rule purport to change the research protections afforded to biospecimens, but would nevertheless leave individuals inadequately protected. There is a range of ways that clinical samples can be used without consent under this proposal. For example, identifiable private information obtained in the clinic can be used in research merely by providing notice to individuals that their information may be used.[199] Identifiable biospecimens can be used in research without consent—the consent requirement can be waived—if research could not otherwise be practicably carried out,[200] although the stringency of this requirement is not yet clear. Finally, even the limited protections afforded to biospecimens are not applicable to the genetic data that results from sequencing the biospecimens, as genetic sequence data is afforded essentially no protections.[201] Newborn samples also receive minimal protections under this proposal. The collection and testing of newborn samples would be excluded from the Common Rule protections,[202] and subsequent research using the samples would generally be considered exempt.[203] Finally, an overarching weakness of the proposal is that it delineates protections

195 Newborn Screening Saves Lives Reauthorization Act of 2014, Pub. L. No. 113-240, 128 Stat. 2851 (2014).

196 Bearder v. Minnesota, 806 N.W.2d 766, 776 (Minn. 2011); Complaint at 4–5, Beleno et al. v. Tex. Dep't of State Health Servs., No. SA-09-CA-0188-FB (W.D. Tex. Mar. 12, 2009).

197 Newborn Screening Saves Lives Reauthorization Act, 128 Stat. 2851. Additionally, the Act is silent as to whether research involving newborn blood samples collected in the future can be *exempt* from the requirements of the Common Rule. *See id.*

198 *Id.*

199 Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 54049 (Sept. 8, 2015).

200 *Id.* at 54054.

201 *Id.* at 53945.

202 *Id.* at 54045.

203 *Id.* at 54049.

with the supposition that biospecimens are essential de-identified.[204] As discussed in Section IV.B, reliance on de-identification is problematic.

Therefore, even in the relatively highly regulated realm of biomedical research, a wide array of research can be conducted without consent or third-party review, thereby leaving individuals inadequately protected.

B. *Commercialization*

In addition to the concerns raised by research generally—including concerns about the nonconsensual use of and limited oversight for research using population-wide genetic data—commercialization raises additional concerns. A key concern is who benefits from the use of genetic data.[205] People are generally willing to share their genetic material altruistically with the research community to bring about the biomedical advances that are thought to redound to the benefit of all.[206] People are less inclined to be altruistic if they know that commercial ventures are likely to profit off their contribution.[207]

A great deal of commercial use of genetic data relies on excised medical waste. In fact, "the growing demand for human tissue samples has sparked an increase in the value of such samples."[208] Even the College of American Pathologists has acknowledged that "medical establishments routinely sell unknowing patients' tissue to biotechnology companies."[209] The justification given is "finders keepers."[210]

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204 *Id.* at 56046; *id.* at 53973 ("[C]onsent would not be required for the secondary research use of non-identified private information, such as the research use of medical records that have had all identifiers removed.").

205 For example, the Common Rule NPRM suggested that "[a] statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit" be included in informed consent documents. *Id.* at 54053.

206 *Id.*

207 *See* Becca Aaronson, *Lawsuit Alleges DSHS Sold Baby DNA Samples*, TEX. TRIB. (Dec. 8, 2010), http://www.texastribune.org/2010/12/08/lawsuit-alleges-dshs-sold-baby-dna-samples (including a parent's observation that, "It's one thing to opt in to a research program that's non-profit; it's another thing to have your DNA or your kid's DNA used by a company to make millions of millions of dollars"); Zubin Master, *Obama's Precision Medicine Plan and the New American National Biobank*, ALB. MED. C.: BIOETHICS TODAY (Feb. 26, 2015), http://www.amc.edu/BioethicsBlog/post.cfm/obama-s-precision-medicine-plan-and-the-new-american-national-biobank ("Participants may be reluctant to enroll and freely give their samples if the biobank had even some commercialization motives.").

208 Dunn, *supra* note 26, at 643.

209 *Id.*

210 *Id.* That is not to say that everyone endorses this approach. In fact, the American Medical Association's Code of Ethics states specifically that "[h]uman tissue and its products may not be

Although there has been commercial use of newborn blood samples, the extent of such use is not well documented. For example, the Texas newborn bloodspots lawsuit uncovered that the state sold blood samples to commercial pharmaceutical companies and profited from trading bloodspots for half a million dollars in lab supplies and services from a private company.[211]

Commercial use of criminal databases is similarly underexplored. To the extent that governmental authorities—including, as discussed above, those in Alabama and Michigan—allow medical research using their criminal databases, commercial entities conducting research would presumably be granted similar research access.[212]

DTC genetic testing companies eagerly cultivate partnerships with commercial ventures. Anne Wojcicki, CEO of 23andMe, acknowledged, "We do a lot of partnerships with a lot of pharma companies because we do feel like that's in the best interest of the consumer in order to make meaningful discoveries from the data."[213] In 2014 alone, 23andMe entered into fourteen collaborative deals with leading pharmaceutical companies (including Genentech and Pfizer) that "focus[ed] on creating databases for specific diseases."[214] These deals included sharing "anonymized data on 650,000 of its customers with Pfizer,"[215] and being paid "up to $60 million by Genentech for access to 3,000 of the DNA samples in its database."[216] AncestryDNA is similarly hoping to cultivate these lucrative partnerships.[217]

In many ways, commercial endeavors are less heavily regulated than federally funded research endeavors. Much research carried out by commercial entities falls outside the Common Rule's reach.[218] Additionally, commercial entities are unlikely to be "covered entities" subject to HIPAA's Privacy Rule.[219] Commercial use of genetic data could, in some cases, instead fall under the FDA regulations that are

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used for commercial purposes without the informed consent of the patient who provided the original cellular material." CODE OF MEDICAL ETHICS, Op. 2.08 (AM. MED. ASS'N 2009).

211 *See* Aaronson, *supra* note 207.

212 *See supra* notes 177–79 and accompanying text.

213 Ramsey, *supra* note 114.

214 *Id.*

215 Palmer, *supra* note 115.

216 Stevens & Marchant, *supra* note 13.

217 Hernandez, *supra* note 77.

218 *See* 45 C.F.R. § 46.101(a) (2015) ("[T]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.").

219 The Privacy Rule applies to "covered entities," which encompasses "any health care provider who transmits health information in electronic form" in certain circumstances. Examples of health care providers include hospitals, physicians, dentists, and other practitioners. OCR PRIVACY BRIEF—HIPAA, *supra* note 82.

parallel to the Common Rule.[220] Those FDA regulations, however, apply only to specific situations and only cover "trials relied upon to determine and establish a product's safety and efficacy."[221] FDA regulations do not apply to "studies necessary for obtaining patent protections, Phase IV trials, or generally, where the company and/or sponsor are seeking to identify genetic predispositions to traits or illnesses but are not seeking to create a drug or device that would require FDA approval."[222]

In cases in which individuals have challenged the nonconsensual, commercial use of their samples, courts have generally been unreceptive to their arguments. The first court to consider the issue was the Supreme Court of California in the seminal case of *Moore v. Regents of the University of California*,[223] a case that has been "cited more than 4,000 times" and adopted in "virtually every jurisdiction to consider the question."[224] Plaintiff John Moore was undergoing treatment for hairy-cell leukemia when his doctor, David Golde, recommended that Moore's spleen be excised to halt progress of his disease.[225] Golde did not mention, however, that he intended to retain Moore's excised tissue for subsequent commercial use, nor did he obtain Moore's consent to do so.[226] The court held that Golde's failure to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment" could give rise to a claim of breach of fiduciary duty or lack of informed consent.[227] The court did not, however, hold that physicians generally must disclose the mere intent to retain excised tissue if this decision would not affect the physician's personal judgment. In fact, the court noted that Moore "clearly did not expect to retain possession of his cells following their removal"—language that echoes the standard for abandonment.[228]

In *Greenberg v. Miami Children's Hospital Research Institute*, parents of children afflicted with Canavan disease, who came together and developed a Canavan registry that contained epidemiological data about the families along with genetic material, brought suit.[229] After Dr.

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220 These regulations are, to some extent, more stringent than the Common Rule in that the process for exemption and waiver is unavailable for covered research. *See infra* Part IV.

221 Koch, *supra* note 81, at 61.

222 *Id.* at 61–62.

223 Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

224 Render, *supra* note 75, at 574–75.

225 *Moore*, 793 P.2d at 480–81.

226 *Id.* at 481.

227 *Id.* at 485.

228 *Id.* at 488.

229 Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

Matalon, the researcher affiliated with the registry, isolated the gene responsible for Canavan disease, he applied for, and was granted, a patent.[230] In response to a claim by family members that the researcher did not notify them of an intent to patent, the court held that imposing a duty to provide informed consent regarding intent to patent "would be unworkable and would chill medical research."[231] The court found that an individual's "property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party."[232]

In a third leading case, *Washington University v. Catalona*,[233] the question before the U.S. Court of Appeals for the Eighth Circuit was "whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party."[234] The Eighth Circuit concluded that the answer to this question was no.[235] In reaching this conclusion, the court noted that surgical patients could not "reasonably have anticipated that they had any right to have excised materials returned to them following surgery."[236]

Much like with use in research, the commercial use of genetic data generally does not require informed consent, nor is it subject to third-party review. Unlike with general research use, however, individuals are more resistant to contributing. In cases where individuals have pushed back against the nonconsensual use of their genetic data, courts have generally been unsympathetic to their claims out of concern for chilling research and based on notions that the samples were abandoned at the outset.

C. *Criminal Proceedings*

When people engage in interactions that lead to the collection of genetic data, they have little expectation that their data could subsequently be accessed and used by the criminal justice system. In fact, nonconsensually obtained genetic samples are increasingly accessible to the criminal justice system.

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230 *Id.*
231 *Id.* at 1070.
232 *Id.* at 1075.
233 Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007).
234 *Id.* at 674.
235 *Id.*
236 *Id.* at 676.

Excised medical waste samples can be made available to law enforcement under HIPAA's Privacy Rule. Although the Privacy Rule generally prevents disclosure of identifiable biospecimens without authorization, the law contains a carve-out for law enforcement.[237] A "covered entity" is permitted to disclose biospecimens to law enforcement when presented with either a court order, a grand jury subpoena, or an administrative request that "allege[s] that the information sought is relevant for law enforcement purposes."[238] Importantly, administrative requests do not require a showing of probable cause.[239]

Although newborn screening samples in the United States have generally remained inaccessible to law enforcement,[240] there is little guarantee that they will stay that way. In Australia, newborn blood samples are made available to police to identify human remains and forensic samples suspected to come from victims of crimes.[241] Moreover, many argue that granting law enforcement access to newborn genetic data could create a population-wide genetic database useful in solving crimes, and one that could help rectify "the disproportionate minority representation in forensic databases."[242]

Law enforcement has demonstrated an interest in accessing genetic data collected and stored by DTC companies. In March 2015, law enforcement made use of publicly accessible Ancestry.com databases; as a result, the company made this database inaccessible to the public.[243] In October 2015, 23andMe published a "transparency report" highlighting requests received from law enforcement to access its database, each of which 23andMe claims to have denied.[244] It is increasingly likely, therefore, that when law enforcement is faced with genetic material that does not match a CODIS profile, it will seek access to commercial databases that contain millions of genetic profiles, one of which is a potential match.

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237 45 C.F.R. § 164.512 (f)(l)(i)–(ii) (2015).

238 Rothstein & Talbott, *supra* note 161, at 157–58.

239 *Id.* at 158.

240 *See, e.g.*, *What Happens to the Blood Sample*, BABY'S FIRST TEST, http://www.babysfirsttest.org/newborn-screening/what-happens-to-the-blood-sample (last visited Feb. 3, 2016) ("Privacy protections and patient confidentiality rules ensure that blood spots cannot be accessed by a third party, including insurers and law enforcement.").

241 *See* Elster, *supra* note 89, at 184.

242 Suter, *Newborn Screening*, *supra* note 46, at 755 n.133.

243 *See* Claire Maldarelli, *23andMe Discloses Police Requests for Customers' DNA*, POPULAR SCI. (Oct. 22, 2015), http://www.popsci.com/23andme-publishes-transparency-report-that-reveals-authority-dna-requests.

244 *Transparency Report*, 23ANDME, https://www.23andme.com/transparency-report (last updated Mar. 1, 2016).

Unlike the HIPAA and Common Rule-based protections in research and commercial use, in the criminal context, limits and oversight come from the Fourth Amendment's prohibition against unreasonable searches and seizures.[245] Generally, for a search or seizure to be considered reasonable, the government must obtain a search warrant whereby law enforcement officers "demonstrate to a neutral magistrate that they have probable cause to believe that the search will reveal particular evidence of a crime."[246] Police activity constitutes a Fourth Amendment "search" only if people exhibit both an actual expectation of privacy and one that "society is prepared to recognize as 'reasonable'" in the items searched.[247] Police activity is considered a "seizure" if it involves a "meaningful interference with an individual's possessory interests in that property."[248]

When blood is "collected from prisoners and parolees for inclusion into state and federal DNA databanks,"[249] the Fourth Amendment clearly applies.[250] This genetic material is not "knowingly exposed" when the samples are obtained; in fact, government officials must "intrude upon the physical boundaries of the body to retrieve it."[251]

In the growing number of instances that police seek "abandoned DNA" from criminal suspects,[252] "existing Fourth Amendment law appears not to apply at all."[253] As Elizabeth Joh observed:

> In more conventional police investigations, the Fourth Amendment poses clear restraints on police investigation. In most circumstances they must obtain a warrant, for example, to enter one's home, even if only to read the newspaper inside. In cases involving "abandoned DNA," however, the police have been able to retrieve the most

245 U.S. CONST. amend. IV.

246 Lowenberg, *supra* note 150, at 1300.

247 Katz v. United States, 389 U.S. 347, 361 (1967) (Harlan, J., concurring).

248 United States v. Jacobsen, 466 U.S. 109, 113 (1984).

249 Joh, *supra* note 132, at 864 (citing United States v. Kincade, 379 F.3d 813, 836–39 (9th Cir. 2004)).

250 *See* Polonsky, *supra* note 127, at 1337–40 ("[Courts] have uniformly considered sample extraction to be governed by the Fourth Amendment and have agreed that the taking of a blood sample amounts to a 'search,' which is barred by the Fourth Amendment absent probable cause.").

251 Joh, *supra* note 132, at 864 (citing Skinner v. Ry. Labor Execs. Ass'n, 489 U.S. 602, 616 (1989)).

252 *Id.* at 858. Abandoned crime scene DNA is increasingly being used in unconventional ways. For example, a new computer program can generate pictures based solely on DNA found at the scene of a crime. Though the science is still evolving, phenotyping programs are being used to project specific traits, like hair and eye color, and are gradually being adopted by law enforcement agencies. *See* Andrew Pollack, *Building a Face, and a Case, on DNA*, N.Y. TIMES, Feb. 24, 2015, at D1.

253 Joh, *supra* note 132, at 865. For a full analysis of this topic, see *id.* at 863–64; *see also* Pollack, *supra* note 252.

> detailed genetic information, without being subject to the criminal procedure rules that normally apply to searches and seizures.[254]

Cases that have considered the issue of "abandoned" DNA have concluded that "there is no objective expectation of privacy in saliva—and the DNA contained within it—that is left behind on a coffee cup or on a smoked cigarette."[255] Accordingly, "abandoned DNA is properly characterized as lacking Fourth Amendment protection."[256]

The logic that courts have used in applying the Fourth Amendment to abandoned cigarettes and coffee cups may extend to criminal investigatory use of databases and medical waste. At least one court has specifically considered the extent to which the Fourth Amendment applies in the case of medical waste. In *Venner v. State*,[257] the Maryland Court of Special Appeals considered whether the Fourth Amendment applied to police collection of medical waste.[258] The court stated:

> It could not be said that a person has no property right in wastes or other materials which were once a part of or contained within his body, but which normally are discarded after their separation from the body. . . . But it is all but universal human custom and human experience that such things are discarded—in a legal sense, abandoned—by the person from whom they emanate . . . . By the force of social custom, we hold that when a person does nothing and says nothing to indicate an intent to assert his right of ownership, possession, or control over such material, the only rational inference is that he intends to abandon the material.[259]

There is certainly a growing awareness of the extent to which law enforcement could gain access to data collected for research.[260] One form of protection available to researchers is called a "certificate of confidentiality," which allows researchers to resist disclosure of study participants' identities, even if that information is subpoenaed.[261] Those conducting research may apply for a certificate of confidentiality if their research involves the collection of sensitive information from human

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254 Joh, *supra* note 132, at 862 (footnotes omitted).

255 *Id.* at 865; *see also, e.g.*, State v. Wickline, 440 N.W.2d 249, 253 (Neb. 1989) (rejecting defendant's argument that the police were required to obtain a warrant before collecting and testing his cigarettes left at the police station because he "abandoned these items and sufficiently exposed them to the officer and the public to defeat his claim to fourth amendment protection").

256 Joh, *supra* note 132, at 869.

257 Venner v. State, 354 A.2d 483 (Md. Ct. Spec. App. 1976).

258 *Id.* at 491.

259 *Id.* at 498–99.

260 Leslie E. Wolf et al., *Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice*, 43 J.L. MED. & ETHICS 594 (2015).

261 *See Frequently Asked Questions*, NAT'L INST. HEALTH, http://grants.nih.gov/grants/policy/coc/faqs.htm#3 (last visited Apr. 27, 2016) ("What is a Certificate of Confidentiality?").

participants.[262] Certificates of confidentiality permit researchers to avoid compelled disclosure in a range of proceedings, although they only cover data collected while the certificate is in effect.[263] Moreover, certificates of confidentiality still permit a range of voluntary disclosures.[264] Certificates of confidentiality are only obtained in a small percentage of cases, thereby providing even more limited protection against access to genetic databases by law enforcement.[265]

IV. THE UNTENABLE JUSTIFICATIONS FOR COLLECTION AND USE WITHOUT CONSENT

A number of justifications—both legal and ethical—are given for the nonconsensual collection and use of genetic data. Medical waste can be collected without consent because it has been abandoned.[266] Genetic data can be used in research without consent because it has been de-identified.[267] Newborn blood samples can be collected for subsequent use without consent because they are extremely useful, and there is concern that obtaining consent could cause the number of available samples to decline.[268] Recognizing donors' ongoing interests in their samples could potentially impede important biomedical progress.[269] This Part considers the proffered justifications for nonconsensual collection and use.

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262 *See id.* ("Who may apply for a Certificate of Confidentiality?").

263 *See id.* ("What is a Certificate of Confidentiality?"); *see also Certificates of Confidentiality: Background Information*, NAT'L INST. HEALTH, http://grants.nih.gov/grants/policy/coc/background.htm (last visited Apr. 27, 2016) ("A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.").

264 *See* OFFICE OF HUMAN RESEARCH PROTS., GUIDANCE ON CERTIFICATES OF CONFIDENTIALITY (2003) ("Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.").

265 *See, e.g.*, Brett A. Williams & Leslie E. Wolf, *Biobanking, Consent, and Certificates of Confidentiality: Does the ANPRM Muddy the Water?*, 41 J.L. MED. & ETHICS 440, 444–45 (2013) (noting that "a 2003 study of 12 major U.S. repositories reported that only one had obtained a Certificate" and that "only about one-quarter of IRBs would require or recommend a Certificate for biobanks").

266 *See infra* Section IV.A.

267 *See infra* Section IV.B.

268 *See infra* Section IV.C.

269 *See infra* Section IV.D.

A. *Abandonment*

Abandonment, one of the leading justifications for the nonconsensual collection of medical waste, involves initial owners giving up their interest in property and transferring ownership unilaterally to the first person who takes possession—a form of "finders keepers."[270] Common law abandonment has two requirements: "First, the owner must [intend] to relinquish all interests in the property . . . . Second, there must be a voluntary act by the owner effectuating that intent."[271] In the context of medical waste, the fact of its abandonment is all but assumed.[272] For example, Natalie Ram succinctly concludes that "waste material is sure to be considered abandoned property."[273]

Determining that property is abandoned has far-reaching implications. In the civil context, property law "provide[s] little recourse" to individuals deemed to have abandoned their property.[274] Property considered abandoned "may be used without permission for any purpose."[275] In the criminal context, genetic material considered abandoned can be collected and used without the protection of the Fourth Amendment.[276] In other words, when genetic material is considered abandoned, it can be collected "from anyone, at any time."[277] Although abandonment is the justification for both the nonconsensual collection of medical waste and the collection and use of genetic data in the criminal context, it is not entirely clear that the requirements for abandonment are actually met in either of these cases.

The first question presented is whether individuals can, in actuality, abandon their genetic sequence in the same way and with the

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270 *See* Ram, *Assigning Rights*, *supra* note 76, at 171.

271 Lior Jacob Strahilevitz, *The Right to Abandon*, 158 U. PA. L. REV. 355, 375–76 (2010); *see also* United States v. Thomas, 864 F.2d 843, 846 (D.C. Cir. 1989) ("To determine whether there is abandonment in the fourth amendment sense, the . . . court must focus on the intent of the person who is alleged to have abandoned the place or object."); Griffis v. Davidson Cty. Metro. Gov't, 164 S.W.3d 267, 272 (Tenn. 2005) ("[A] complainant . . . must show both intent to abandon for the stated limitations and some external act or omission by which the intent to abandon is effectuated."); Scherr, *supra* note 4, at 465–66 ("Abandonment requires knowledge and intention. Without a showing that individuals knew that by their conduct they had abandoned their expectation of genetic privacy in their DNA, no abandonment has occurred." (footnote omitted)).

272 *See supra* Section II.A.

273 Ram, *Assigning Rights*, *supra* note 76, at 172.

274 *Id.* at 171.

275 *Id.*

276 Scherr, *supra* note 4, at 447 ("Surreptitious DNA harvesting by the police is currently unregulated by the Fourth Amendment. The few courts that have addressed the issue consistently find that the police are free to harvest DNA abandoned by a putative suspect in a public place.").

277 Joh, *supra* note 132, at 859.

same implications that one could abandon a sofa that is no longer wanted on a curbside. Unlike with curbside furniture, physical separation does not terminate all ongoing interests in the genetic material; our genetic information—the code unique to each and every one of us—is still a part of every cell in our body.[278] Another person's decision to collect and use our genetic information without consent has meaningful implications for us to an extent that another's decision to collect and reupholster an abandoned sofa does not. When people leave furniture on the curb, they understand—either intuitively or by studying the law—that they no longer have a claim to the furniture once someone else has picked it up and taken it.[279] In other words, they intend to relinquish all interests in the furniture. The same cannot be said for the things we inadvertently discard that contain genetic material—the hair we shed, the fingerprints and saliva we leave behind. There is little that suggests that, even if we abandon our discarded hair, we intend to relinquish all interests—including genetic ones—in that property.[280]

The second question is whether individuals, through their actions, undertake a voluntary act that demonstrates an intent to abandon their genetic material. Certainly, individuals shed their genetic material throughout the day—genetic material is found in the skin cells, hair, and saliva that we inadvertently leave behind.[281] But it is not at all clear that the shedding or leaving behind of genetic material is sufficiently voluntary so as to demonstrate the requisite intent to abandon the genetic sequence and all information contained therein.[282] As Elizabeth E. Joh states:

> The volition that is implied in abandonment is simply unrealistic here. Courts may readily find that criminals have clearly intended to renounce all privacy claims to bags containing illegal firearms or to packages of drug paraphernalia when fleeing the police, but we hardly have a realistic choice in shedding DNA. One can shred private papers or burn garbage so that no one may ever delve into them, but leaving DNA in public places cannot be avoided.[283]

In the criminal context, Albert Scherr makes a compelling argument that, for essentially these reasons, the Fourth Amendment analysis

278 *See, e.g.*, PRIVACY AND PROGRESS, *supra* note 5, at 16–17.

279 *See, e.g.*, Strahilevitz, *supra* note 271, at 373.

280 *See, e.g.*, PRIVACY AND PROGRESS, *supra* note 5, at 74.

281 *See* Scherr, *supra* note 4, at 465–66.

282 *Id.*

283 Joh, *supra* note 132, at 867 (footnote omitted); *see also id.* at 873 ("Custom may suggest that we intend to abandon human waste, but the assumption that we do so, and thus implicitly authorize DNA analysis on the same waste, is hardly a widely accepted part of our social experience.").

generally accepted by courts—that collection of abandoned genetic material does not implicate Fourth Amendment concerns because individuals have abandoned their reasonable expectation of privacy—is wrong.[284] Scherr makes clear that Fourth Amendment determinations about privacy are not merely about what is accessible to the public.[285] As the Supreme Court stated in *Katz v. United States*, "[W]hat [an individual] seeks to preserve as private, even in an area accessible to the public, may be constitutionally protected."[286] Although genetic material that is left behind is accessible to the public, it is entirely possible that individuals retain an expectation of privacy in their unique genetic sequence. As Scherr observes:

> It is speculative, at best, to conclude from a silent record that individuals would know that they were shedding DNA; that they were aware of the ability of the government to collect that DNA, analyze it, and use it as an identification tool; or that they were cognizant of the other kinds of uses the police could make of their DNA, let alone the scope and breadth of genetic information about them that might be available to those with access to it via the appropriate technology.[287]

Relying on abandonment as justification for the nonconsensual collection of medical waste and the nonconsensual collection and use of "abandoned" DNA in the criminal context requires accepting that individuals who submit blood for a cholesterol screening—or who walk through a crime scene—*intend* to relinquish all interests in their genetic material and that they have undertaken a voluntary act to effectuate this intent. The facts and circumstances of these types of encounters cast doubt on both propositions.

B. *De-Identification*

A critical justification for the nonconsensual use and sharing of genetic data, particularly in research, is that the samples have been de-identified—stripped of certain identifying pieces of information (such as name or social security number).[288] De-identification makes the identity of the source harder to discern such that collecting, storing, sharing, and

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284 *See* Scherr, *supra* note 4.

285 *Id.*

286 Katz v. United States, 389 U.S. 347, 351 (1967).

287 Scherr, *supra* note 4, at 466 (footnote omitted).

288 *See, e.g.*, Suter, *Newborn Screening*, *supra* note 46, at 768–69 ("The current system and recommended approach of some scholars and professional groups might be considered a compromise of sorts; informed consent is required if the samples are identifiable, but otherwise consent is not required for anonymized or de-identified samples.").

using genetic data are arguably less likely to cause harm to the source.[289] Unfortunately, de-identification as a justification for nonconsensual use does not withstand closer examination.[290]

First, de-identification of genetic materials does not work: genetic materials are never truly "de-identified."[291] De-identification as a process commonly used with certain types of medical information does not work particularly well with genetic data—something inherently unique to each individual and that has elements in common with biologically-linked family members.[292] Even proposed modifications to the Common Rule recognize "advances that have come in genetic and information technologies . . . make complete de-identification of biospecimens impossible and reidentification of sensitive health data easier."[293]

A headline-grabbing 2013 article published in *Science* made the inadequacy of de-identification procedures for genetic data clear.[294] In the article, lead author Melissa Gymrek and colleagues described their ability to identify genetic material that had been de-identified in accordance with HIPAA.[295] Using only the source's year of birth and state of residency—traditionally thought of as "weak identifiers"[296]—the researchers were able to identify the source by comparing sections of an individual's genetic sequence to genetic sequences uploaded and shared in free and publicly accessible databases.[297] Through this process, researchers were able to identify the surnames of approximately twelve percent of Caucasian males.[298] In the wake of this discovery, geneticist and scholar Amy L. McGuire observed that "[t]o have the illusion you

289 *See* Yaniv Erlich et al., *Redefining Genomic Privacy: Trust and Empowerment*, PLOS BIOLOGY (Nov. 4, 2014), http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1001983.

290 *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44524 (July 26, 2011) ("[W]e recognize that there is an increasing belief that what constitutes 'identifiable' and 'de-identified' data is fluid; rapidly evolving advances in technology coupled with the increasing volume of data readily available may soon allow identification of an individual from data that is currently considered de-identified. In this sense, much of what is currently considered de-identified is also potentially identifiable data.").

291 Sgambati, *supra* note 165, at 88 ("DNA, by its very nature, cannot be 'deidentified' in the way that traditional data can be and is required to be by Institutional Review Boards (IRBs), which review and approve human research.").

292 *Id.* at 88–89 ("DNA is inherently unique to each individual and a DNA profile can be linked back to its origin as well as linked to individuals closely related to the origin.").

293 76 Fed. Reg. at 44525.

294 *See* Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321 (2013).

295 *Id.* at 322.

296 *Id.*

297 *Id.* at 321–22.

298 *Id.* at 322.

can fully protect privacy or make data anonymous is no longer a sustainable position."[299]

Second, even if de-identification did work, there is a tradeoff between identifiability of the biospecimen and its usefulness, particularly when biospecimens are de-identified to the point of anonymization—stripped of all identifiers in a way that makes it impossible for anyone to re-identify individuals.[300] As has been recognized, "the more data is removed . . . the more scientific value is lost; the more data is kept, the less the data is truly anonymized."[301] Because the point of using genetic data is to assess the extent to which genes, rather than environment or lifestyle choices, cause certain outcomes, de-identifying or truly anonymizing biospecimens withholds information helpful to that assessment.[302]

Finally, even if genetic materials could effectively be de-identified and not linked to a particular individual, the results of their nonconsensual use could nevertheless cause harm.[303] Genetic material collected from a closed group or population could reveal information about members of the group that end up stigmatizing individual members of that group, including the source.[304] For example, research using genetic samples collected from a particular tribe of Native Americans (the Havasupai) was supposed to be conducted only for diabetes research. The samples were subsequently used, however, allegedly without consent, for research on a host of other conditions including schizophrenia and inbreeding—results that could potentially stigmatize the tribe collectively and members of the tribe as individuals.[305]

Given that de-identification as a process is no longer able to protect the identity of individuals, and that de-identification cannot protect

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299 Gina Kolata, *Web Hunt for DNA Sequences Leaves Privacy Compromised*, N.Y. TIMES (Jan. 17, 2013), http://www.nytimes.com/2013/01/18/health/search-of-dna-sequences-reveals-full-identities.html; *see also* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53940–41 (Sept. 8, 2015) ("As analytic techniques become more sophisticated and large datasets become more accessible, it will not be possible to guarantee that an individual could never be identified from a biospecimen or combination [of] data sources, particularly if whole genome sequencing is conducted.").

300 *See* Matthew J. Piehl, *The Brave New World of Genetic Biobanks: International Lessons for a Potential United States Biobank*, 46 VAL. U. L. REV. 69, 77 (2011).

301 *Id.* at 78 (alteration in original) (quoting Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 353 (2007)).

302 *See* Ram, *Assigning Rights*, *supra* note 76, at 131–32.

303 *See* Hsieh, *supra* note 16, at 367.

304 *See* Geetter, *supra* note 79, at 45 ("[E]ven if individual biological specimens are de-identified before future use, the results of genetic testing may stigmatize a group if a genetic or other conditions are shown to be more prevalent in certain communities.").

305 *See* Koch, *supra* note 81, at 55.

members of a closed population, de-identification is no longer a supportable justification for nonconsensual collection and use of genetic data.

C. *Utility*

A third argument against obtaining informed consent is that requiring consent could hamper access to genetic materials. Some scholars have observed that "[a]ny system requiring any kind of consent will take time and money that might be better spent on research itself. Furthermore, some patients will refuse."[306] Others argue that granting individuals a right to provide informed consent to subsequent use of their genetic information could impede genetic research by increasing the transaction costs of obtaining access to genetic material, potentially hampering important biomedical advances.[307]

While these arguments have obvious intuitive appeal, the empirical data does not bear out this conclusion. With regard to newborn blood samples, data show that parents are particularly willing to allow research to be conducted using their newborns' genetic data. A 2008 study, for example, found that ninety percent of mothers would agree to have their child's sample included in a biobank "with no restrictions on the type of research performed."[308] In a second study, seventy-five percent of parents were willing to share their child's sample if asked beforehand.[309] A third study found that parents were far more willing to allow their child's newborn blood sample to be used for research if asked, with about seventy-six percent of parents willing to share the sample with researchers if consent was obtained, and only about twenty-eight percent willing to share the sample if consent was not obtained.[310]

The empirical data is much the same in the context of medical waste. A recent study conducted among 220 postoperative surgical patients found that 96.3% of patients indicated that they would not object to their tissue being used in research.[311] In a survey of veterans consulted about a genetic database for the Veterans Administration,

306 van Diest & Savulescu, *supra* note 39, at 648.

307 *See, e.g.*, Bregman-Eschet, *supra* note 28, at 25.

308 Suter, *Newborn Screening*, *supra* note 46, at 775.

309 *See* Tan, *supra* note 53 ("According to a study by Case Western Reserve University's bioethicist Aaron Goldenberg, 75% of parents would be willing to have their child's blood used in biomedical research, if they were asked beforehand.").

310 *See* Suter, *Newborn Screening*, *supra* note 46, at 775. Of course, if consent is not required, it does not matter how willing parents are, because the sample can be collected and used regardless.

311 *See* R.J. Bryant et al., *Ownership and Uses of Human Tissue: What are the Opinions of Surgical In-Patients*, 61 J. CLINICAL PATHOLOGY 322, 322 (2008).

nearly eighty percent said "they would be comfortable providing access to residual clinical samples for research," eighty-three percent said a database "should definitely or probably be created," seventy-one percent said "they would definitely or probably participate," and seventy-seven percent agreed that it is "a good idea to use leftover blood or tissue for research purposes."[312] In a survey of Kaiser Permanente enrollees asked about the creation of a biobank, even though sixty-seven percent of respondents had not previously heard of biobanks, sixty-nine percent said that they would be willing to "provide an additional tube of blood to be stored in the biobank for future research" in large part because it is "import[ant] to contribute to future research."[313]

Justifying the nonconsensual collection or subsequent nonconsensual use of genetic data on the basis of utility ignores the empirical data suggesting that people are particularly willing to share their genetic data, particularly if they are given an opportunity to consent.[314] It also demonstrates a willingness to use genetic data even from people who are demonstrably unwilling to share it. Respecting individual autonomy is important both for its consequences—including maintaining trust in the enterprise—but also normatively so as not to use people as mere means toward an end. If providing the opportunity to consent "thereby reduc[es] the number of samples available for research, providing such choice is a requirement of respectful engagement with the contributors."[315]

Some may argue that granting individuals the right to consent, with the attendant risk that some percent of the individuals sampled might opt out, could introduce the possibility of selection bias and skew databases in ways that have meaningful implications for the research results. The reality is that databases today are already skewed in ways that are consequential. For example, one study found that less than ten percent of the genetic material in certain research studies was of non-European descent.[316] A 2010 Government Accountability Office report found that none of the leading DTC genetic tests could provide complete results for African American and Asian donors because "most genetic research has only been done on persons of European ancestry and therefore such individuals receive more accurate results."[317] Given

312 Kaufman et al., *supra* note 61, at 787–89.

313 Rahm et al., *supra* note 80, at 445–47.

314 *See* Suter, *Newborn Screening*, *supra* note 46, at 775.

315 Javitt, *supra* note 22, at 751.

316 *See* Charles N. Rotimi, *Health Disparities in the Genomic Era: The Case for Diversifying Ethnic Representation*, 4 GENOME MED. 65 (2012).

317 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-847T, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES 10 (2010).

the paucity of diversity already extant in today's databases, it is not clear that even a twenty-five percent rate of individuals opting out would lead to a less representative sample than already exists.

D. *Concerns About Ongoing Interests*

One of the concerns courts have articulated in the context of commercialization is that recognizing any ongoing interest in excised medical waste is tantamount to permitting individuals to exercise "dead hand" control over the excised waste—a right to assert an interest in a way that could thwart the work of researchers and others. For example, in *Greenberg v. Miami Children's Hospital*,[318] the court observed that imposing a duty on researchers to disclose an intent to patent inventions relying on excised medical waste "would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses."[319] And the *Moore* court noted that researchers often use biospecimens collected years or even decades earlier and that "if lingering, undefined interests could be retained" and asserted, biomedical progress "would surely be hindered."[320] This is true in large part because those considering ongoing interests in bodily tissue tend to think exclusively in terms of property rights.[321] Even the Nuffield Council on Bioethics, in its consideration of biospecimens, "was concerned as to the potential consequences were property law rights to be recognised."[322]

What the analysis misses, however, is that these concerns arise primarily when thinking in terms of granting individuals a property interest in their genetic material—an approach that could, perhaps, have serious implications for the research enterprise by granting individuals ongoing, indefinite control.[323] There are, however, ways to acknowledge

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

319 *Id.* at 1071.

320 Render, *supra* note 75, at 574.

321 *See, e.g.*, Bregman-Eschet, *supra* note 28, at 25 ("[G]ranting an individual property rights over genetic information could impede genetic research by increasing the transaction costs of obtaining access to genetic material and information, which is a growing part of today's medical research.").

322 McHale, *supra* note 63, at 125; *see also* NUFFIELD COUNCIL ON BIOETHICS, HUMAN TISSUE: ETHICAL AND LEGAL ISSUES ¶ 9.13–.14 (1995).

323 *See, e.g.*, *Greenberg*, 264 F. Supp. 2d at 1076 ("If adopted, the expansive theory championed by Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital."); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 377 (2007); Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 748 (2004) [hereinafter Suter,

and respect ongoing interests in genetic material that do not require granting individuals a property right in their genetic data. Permitting individuals to consent to the collection and subsequent use of their genetic material, and providing the additional safeguard of third-party review prior to use, recognizes that individuals have autonomy interests in their genetic material—interests in making decisions about the uses to which their genetic material are put.[324] Informed consent that is implemented at the point of collection, and third-party review conducted prior to use, provide a way to respect these important autonomy interests without granting indefinite ownership rights that could hamper the research enterprise.

V. PROTECTING ONGOING INTERESTS IN THE COLLECTION AND USE OF GENETIC DATA

Given that the justifications for the widespread, nonconsensual collection of genetic data and its subsequent nonconsensual use do not withstand scrutiny, the question then becomes how best to protect individuals' ongoing interests in their genetic material without impeding important biomedical advances that could result. In proposing the Precision Medicine Initiative, the White House demonstrated concern for this very issue. The White House specifically mentioned the importance of considering "whether changes are needed to support the development of this new research and care model, including its critical privacy and participant protection framework."[325]

In the context of collecting population-wide genetic data, however, ensuring adequate protections for individuals' ongoing interests in their genetic data can foster and maintain trust in the research enterprise in a way that helps ensure ongoing access to genetic data. As discussed in Section I.C, trust in systems protects against potential backlash thereby permitting systems to continue. As proposed in the Section below, fostering and maintaining trust in the collection and use of genetic data requires two things: first, it requires obtaining informed consent for the

Privacy] ("[A] strong link between property rights and commodification underlies the biotechnology community's opposition to using property rights to protect privacy. Their objection is not to treating genetic information as property or a commodity per se, but to granting the initial entitlement of property rights in the source of that information. Indeed, their opposition is grounded precisely in their view of genetic information as a commodity, access to which they do not want impeded by such entitlements.").

324 Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53942 (Sept. 8, 2015) ("[T]here is a growing recognition that many people want to have some degree of control over the circumstances in which an investigator can derive information about them . . . .").

325 Precision Medicine Initiative Fact Sheet, *supra* note 9.

collection of genetic materials; and second, it requires third-party review prior to use.[326]

A. *Informed Consent Prior to Collection*

Informed consent has long been a cornerstone of clinical care and biomedical research.[327] In 1947, Nazi-era violations gave rise to the *Nuremberg Code*,[328] which established the foundational principle that the "voluntary consent of the human subject is absolutely essential."[329] In the years since, a number of ethical guidance documents—including the *Declaration of Helsinki*,[330] the Council for International Organizations of Medical Sciences "International Ethical Guidelines for Biomedical Research Involving Human Subjects,"[331] and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use "Good Clinical Practice" (ICH/GCP) standards[332]—have reaffirmed a commitment to ensuring that participants receive sufficient information about the research to "make a voluntary and uncoerced decision whether to participate."[333]

Despite agreement about the ethical justifications for informed consent, and the importance of informed consent in the collection and use of biospecimens,[334] questions remain about how best to implement

326 In addition to the safeguards discussed below, there are practical considerations that must be addressed to effectuate protections of individuals' ongoing interests. For example, as we increasingly move to a realm in which genetic data and information is routinely stored, shared, and accessed electronically, baseline data security and information technology protections should be in place. Without such protections, even enhanced informed consent protections can be rendered meaningless in terms of protecting an individual's autonomy and dignitary interests. *See* Bregman-Eschet, *supra* note 28, at 25–26.

327 *See* Hsieh, *supra* note 16, at 375 ("Requiring a subject's consent before performing medical research has been the pillar of bioethics since the Nuremberg Trials.").

328 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–82 (1949), *reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 2 (George J. Annas & Michael A. Grodin eds., 1992).

329 *Id.* The Nuremberg Code § 1.

330 WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2008).

331 COUNCIL FOR INT'L ORGS. OF MED. SCIS. & THE WORLD HEALTH ORG., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (1993).

332 *See* International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline; Availability, 62 Fed. Reg. 25692 (May 9, 1997).

333 Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?* 283 JAMA 2701, 2706 (2000).

334 *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53938 (Sept. 8, 2015) ("A growing body of survey data show that many prospective participants want to be asked for their consent before their biospecimens are used in research.").

informed consent in the context of the widespread collection, sharing, and use of genetic data. As described in Part III above, for a variety of reasons, consent for the collection of genetic data is not required in a wide range of circumstances. In recognizing that individuals have ongoing interests in their genetic data, and in recognition of the importance of maintaining trust in the widespread collection, storage, sharing, and use of genetic data, this Article advocates for rehabilitating and restoring the role of consent for the collection of genetic data. In making this recommendation, this Article relies in part on work done toward modernizing the Common Rule[335] and the most recent iteration of the *Declaration of Helsinki*, which similarly requires consent for the "collection, storage and/or reuse" of at least identifiable biospecimens and genetic data.[336] The question, though, is how best to implement informed consent. A proposal is set forth below.

1. Opt-in or Opt-out Consent

A threshold question is whether consent to the collection, storage, sharing, and potential subsequent use of genetic data should be opt in or opt out. In many ways, this is simply a question of setting the default from which individuals can choose an alternative. With opt-in consent, biospecimens will not be collected without affirmative consent.[337] Under opt-out consent, the default is that biospecimens *are* collected without consent unless an individual affirmatively opts out.[338] Each approach prioritizes distinct values: opt-in consent prioritizes protecting informed, autonomous choice;[339] opt-out consent prioritizes the collection of biospecimens—potentially at the expense of respecting autonomy—and has the potential to create a more representative collection of samples.[340]

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335 *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44515 (July 26, 2011) ("The general rule would be that a person needs to give consent, in writing, for research use of their biospecimens, though that consent need not be study-specific, and could cover open-ended future research.").

336 WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR RESEARCH INVOLVING HUMAN SUBJECTS 32 (2013), http://www.wma.net/en/30publications/10policies/b3.

337 *See* Noor A.A. Giesbertz, Annelien L. Bredenoord & Johannes J.M. van Delden, *Inclusion of Residual Tissue in Biobanks: Opt-in or Opt-out?*, PLOS BIOLOGY, August 2012, at 1 ("[I]n an opt-out scheme inaction is treated as a signal of consent.").

338 *See* Vermeulen et al., *supra* note 63, at 1505.

339 *See* Giesbertz, Bredenoord & van Delden, *supra* note 337, at 1 ("In an opt-in scheme, a person explicitly expresses his or her consent.").

340 *See* Kaufman et al., *supra* note 61, at 787 ("Opt-out methods may yield high enrollment and, in at least one study, have been shown to result in less biased ascertainment of cases.

If implemented improperly, opt-out consent raises serious ethical concerns.[341] Without adequate information about the potential implications of permitting biospecimens to be collected, providing the right to opt-out cannot justifiably be considered informed consent.[342] In many cases, however, individuals *are* inadequately informed about the consequences given that the result of educating and informing potential donors is that fewer donors are willing to participate; therefore, practitioners have little incentive to provide adequate education and information.[343]

For example, with regard to newborn blood samples, in the midst of litigation, Texas implemented an opt-out consent model under which attending physicians must explain the state's system of retaining and storing bloodspots for future research use.[344] Physicians are not, however, required by law to explain the parents' options nor are they required to return forms to the state.[345] Since the law's passage in 2009, only 6900 Texan parents out of 240,000 births have opted out of the collection of their newborn's genetic material,[346] meaning less than three percent of parents have opted out—a number lower than what would be predicted by empirical data if consent was fully informed and a strong indication that the Texas consent process is inadequate.[347]

With opt-in consent, the incentives are reversed. Because samples cannot be collected for subsequent uses without consent, practitioners have incentives to explain the subsequent use, even if only in general terms.[348]

The ethical implementation of both opt-in and opt-out consent requires adequate awareness, sufficient information, and a genuine opportunity to prevent one's samples from being collected.[349]

Possible disadvantages of this method include enrollment of people who do not wish to participate in the study but fail to opt out . . . ." (footnote omitted)).

341 *See* Gefenas et al., *supra* note 62, at 352.

342 *See* Suter, *Newborn Screening*, *supra* note 46, at 786 ("An opt-out approach is only protective of autonomous decision making it if is *informed* refusal. If parents are not adequately educated about NBS, or even worse that NBS occurs and that they can refuse, the opt-out approach makes a mockery of the notion of autonomous decision making and informed refusal." (footnote omitted)).

343 *See id.* at 782 ("The incentives simply are too few to educate parents under an opt-out as compared to an opt-in approach. Under an opt-out approach, the default is to test, which creates no incentive to discuss NBS with parents.").

344 *See* Carnahan, *supra* note 44, at 308–09.

345 *Id.* at 309.

346 Serrano, *supra* note 43, at 111.

347 *See supra* Section IV.C.

348 *See* Suter, *Newborn Screening*, *supra* note 46, at 782 ("[U]nder an opt-in approach, the default is not to test unless parents consent, which creates strong incentives to discuss NBS with parents, even if only in general terms.").

349 *See* Giesbertz, Bredenoord & van Delden, *supra* note 337, at 1, 3–4.

Accordingly, most who consider the issue realize that the distinction between an ethically implemented opt-in and opt-out consent process is not that stark.[350] The empirical data bears out this similarity. Studies show that the number of people who opt in to a particular condition "is the inverse of those who opt out" when consent procedures are ethically implemented.[351] Accordingly, given the wide range of subsequent uses for genetic data, and that implementing ethical systems of opt-in or opt-out consent require similar resources, this Article advocates for opt-in consent, as it is better able to protect the autonomous decisions of those who do not wish to be included.[352]

2. Specific or Broad Consent

The second question is whether those collecting biospecimens should solicit specific or broad consent. Specific consent is what is generally thought of as informed consent—consent for the use of genetic data for specifically enumerated purposes, the risks and benefits of which are explicitly spelled out.[353] Specific consent grants individuals a measure of "control over the use of [their] sample."[354] Specific consent better ensures that participants actually agree to the use of their genetic data in research.[355] But specific consent, in the context of research using large amounts of already collected genetic data, is often viewed as impractical or impossible.[356]

Broad consent permits a variety of types of consent ranging from consent for specific subsequent uses (e.g., consent for use in research

350 *See* Suter, *Newborn Screening*, *supra* note 46, at 787 ("If providers were to offer the kind of information about NBS that would make the opt-out approach truly informed refusal, the process would be quite close to informed *consent*.").

351 *Id.* at 787; *see also* PRIVACY AND PROGRESS, *supra* note 5, at 92.

352 *See* Kaufman et al., *supra* note 61, at 791 ("On the other hand, more people agreed the opt-in model would respect people's right to choose whether to participate (90%), as compared with the opt-out model (86%); and considerably more people believed the opt-out model would wind up including people in the database who did not really want to participate (47% vs. 27%).").

353 Vermeulen et al., *supra* note 63, at 1505.

354 Hsieh, *supra* note 16, at 380.

355 *Id.* ("Specific consent protects the individual from the risks of unknown research that could potentially lead to adverse consequences.").

356 *See* Piehl, *supra* note 300, at 86–87 ("The alternative would be to seek out permission from each participant for every single new research study. This also appears prohibitively expensive and time-consuming."); Susan E. Kelly & Barbara Prainsack, *Have Research Ethics Committees Got It Wrong? A New Study Looks at What Participants in Medical Research Actually Want*, HUFFINGTON POST (Mar. 24, 2015, 2:30 PM), http://www.huffingtonpost.com/tim-spector/have-research-ethics-comm_b_6924272.html ("Seeking specific informed consent in these circumstances, particularly for each potential new use of samples or information, is challenging, expensive and often practically impossible.").

related to heart disease) to unrestricted consent for all future use, a process sometimes described as blanket consent.[357] Broad consent is considered far more practicable for research involving large numbers of biospecimens.[358] It is considered "particularly helpful in situations where at the time of the initial consent, it is impossible to predict how data and samples will be used in the future."[359] But broad consent also raises concerns, particularly given that specific future uses are not articulated such that any "consent" provided cannot possibly take into account the actual risks and benefits of agreeing to participate.

For matters of practicality and feasibility, this Article endorses broad consent—an approach consistent with at least some data suggesting that this is participants' preferred approach.[360] Importantly, however, this Article endorses letting donors specify the cross-contextual uses that they find permissible. Broad consent can be implemented in a "multi-layered" way, "allowing donors to choose from a number of different options."[361] An individual's consent to permit use of genetic data in research should not automatically render that genetic data accessible to law enforcement, nor should consenting to newborn screening as a public health intervention automatically make a newborn's genetic data available to commercial enterprises.

Although this approach best respects individual autonomy and decision making, the approach likely requires a system of tracking preferences. The Common Rule NPRM already envisions a system of electronic tags that travel with the data,[362] but the agencies considering the modification decided against implementing a more extensive tagging system of a kind that would likely be needed if tracking individual preferences.[363] There is, however, a way of minimizing the burden of any tracking system, which involves giving entities a choice of whether to implement a tracking system. Entities that choose not to track would only be granted access to samples from those who give blanket consent to all uses. Entities that choose to implement a tracking

357 *See* Gefenas et al., *supra* note 62, at 351.

358 *See* Hsieh, *supra* note 16, at 380.

359 Kelly & Prainsack, *supra* note 356.

360 *See* David Wendler, *One-time General Consent for Research on Biological Samples,* 332 BRITISH MED. J., 544 (2006).

361 Gefenas et al., *supra* note 62, at 352.

362 Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53973 (Sept. 8, 2015) ([T]hese institutions might simply 'tag' biospecimens and information as either available or not available for secondary research.").

363 *Id.* at 53974 ("The Common Rule departments and agencies contemplated proposing [tracking preferences] . . . . [I]t was determined that limiting the scope of the broad consent in this manner would be very difficult to implement and would require rigorous tracking on an individual-subject basis.").

system would have access to the more expansive collection of samples from those who give broad consent and specify permitted uses.

3. Implementation

The final consideration is how best to operationalize the ethical safeguard of informed consent for subsequent use at each of the points of collection. In the clinical encounters that give rise to medical waste and newborn bloodspots, generally applicable guidelines should be implemented. For example, consenting to specific clinical procedures that give rise to genetic samples should not be construed as consenting to the subsequent collection and use of these samples. Consent to the collection and subsequent use should therefore be obtained independent of consent to the specific medical procedure.

Moreover, those collecting samples should be mindful of carrying out the consent process at a time when the information is most likely to be understood. In the clinical context, this means not obtaining consent in the immediacy of high-stress encounters. Among patients in one study, there was an "'overwhelming' belief that patients should be given the form several days before the surgery to allow time for reflection or to change their mind."[364] In the context of newborn screening, this may mean not obtaining consent for collection and subsequent use in the immediate aftermath of the child's birth. Instead, the implications of permitting collection and subsequent use could be explained, and consent could be obtained, at a prenatal clinical visit. Alternatively, forms that explain the sharing and subsequent use, and that detail procedures for opting in, could be distributed at birth, to be submitted upon review and consideration at a later date.[365]

Unlike in the clinical context, DTC genetic testing companies generally seek consent for subsequent use of genetic data in research.[366] These companies should establish more robust consent processes than the ones that are currently in place.[367] DTC genetic testing companies specialize in conveying complex and probabilistic information about the consequences of genetic information as it relates to predispositions to disease.[368] These companies should apply this expertise to their informed consent processes for research participation. Consumers

364 Carnahan, *supra* note 44, at 327 (citing ROBERT F. WEIR & ROBERT S. OLICK, THE STORED TISSUE ISSUE 27–28 (2006)).

365 *See id.*

366 *See* Palmer, *supra* note 115; Ramsey, *supra* note 114.

367 *See* Morrison, *supra* note 121, at 592; *see also* Koch, *supra* note 81, at 61–62.

368 *See* Spector-Bagdady & Pike, *supra* note 110.

should be informed about the implications of agreeing to share their genetic data—including that third-party use might not be subject to meaningful limitations. Consumers should also be permitted to limit the contexts in which their genetic data is shared.

Finally, despite this Article's recognition of the importance of informed consent prior to the collection of genetic material, this Article recognizes the competing values at stake in the criminal justice system. The goal of collecting genetic material in the criminal justice system is distinct. It is often about identifying people whose identity is not yet known such that consent could not possibly be obtained.[369] Moreover, the oftentimes retributive or punitive nature of the criminal justice system means that interaction with the system is, at its essence, nonconsensual. This Article, therefore, advocates further consideration of how these values align with informed consent for subsequent use and third-party review prior to use.[370]

B. *Third-Party Review Prior to Use*

Once genetic data has been collected, shared, and stored—preferably in accordance with the informed consent protections set forth above—the question then becomes how best to safeguard individuals' ongoing interests when it comes to subsequent uses. Any answer must recognize the impracticality or impossibility of obtaining consent for each subsequent use—it is often impossible to track down the original source of genetic material given the large amount of genetic data used,[371] and studies suggest that individuals do not, in fact, wish to be contacted with repeated requests to use samples collected long ago.[372]

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369 *See, e.g.*, *A Simplified Guide to DNA Evidence*, CRIME SCENE INVESTIGATOR NETWORK, http://www.crime-scene-investigator.net/simplified-guide-to-dna-evidence.html ("If a case has no suspects to compare the DNA evidence to, the profile of DNA collected at the scene can be entered into the FBI's Combined DNA Index System (CODIS) so that it can be compared to existing DNA records at the local, state or national level. By doing this, investigators may find a positive match to someone whose DNA profile is in CODIS and thereby identify a person of interest.").

370 The Common Rule NPRM proposes to exclude criminal justice use of biospecimens from the informed consent requirements of the Common Rule. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 54045 (Sept. 8, 2015).

371 *See* Geetter, *supra* note 79, at 73 ("[O]btaining informed consent is impracticable, for example, because of the sheer volume of people contributing data and/or biological materials to the initiative or because the data or biological materials were provided in the past . . . .").

372 *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44524 (July 26, 2011) ("An accumulating body of data indicates that while most individuals want to be able to decide whether their biospecimens are available for research, they often do not desire to have

Nevertheless, initial broad consent is insufficient to protect an individual's ongoing interests in their genetic data in the face of potentially limitless future uses.

The World Medical Association recognized this as an essential problem in its recent consideration of biospecimens. The Association recognized not only that broad or one-time consent is insufficient protection, but also that "[s]tringent use of informed consent is unrealistic."[373] The Association, therefore, proposed third-party review to bridge the gap and provide a case-by-case determination of the ethical safeguards necessary to proceed.[374] This Article similarly proposes third-party review to ensure adequate protections given the adoption of broad consent.

Third-party review, like informed consent, is a generally accepted pillar of ethical research.[375] In countries that have implemented population-wide genetic databases, third-party review is a fundamental ethical protection that is routinely implemented.[376]

This foundational ethical requirement tends to get discarded with regard to the subsequent use of genetic data. In the context of research, the Common Rule does away with prior IRB review in a range of circumstances, particularly when the genetic data is "de-identified."[377] In the criminal context, genetic material thought to be abandoned eliminates all Fourth Amendment protections, including prior third-party review by a magistrate.[378] This Article proposes reinvigorating third-party review prior to use in each of the contexts—at a minimum to ensure that subsequent use is consistent with the permissible stated uses in an individual's broad consent. In the research context, IRBs would carry out this review of research proposals relying on genetic data. In the commercial context, regulated research would be similarly

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control over which specific researchers use their samples, for which diseases, at which institutions.").

373 OTMAR KLOIBER, SEC'Y GEN., WORLD MED. ASS'N, DEVELOPING A DRAFT DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS (June 10, 2015).

374 *Id.*

375 *See* Criteria for IRB Approval of Research, 45 C.F.R. § 46.111(a) (2015) (noting that research proposals must be submitted and reviewed in advance by a research ethics committee with authority to prevent trials that do not satisfy these ethical requirements from going forward).

376 Hsieh, *supra* note 16, at 390–91 ("Rather than set rigid requirements, most of the databases prefer to have the flexibility to grant access on a case by case basis. Iceland requires the licensee to submit all research proposals to be approved by an ethics review board. . . . The U.K. Biobank model envisions that a research ethics committee will review all research proposals and that each will have to comply with guidance laid down by the oversight body.").

377 As currently implemented, the protections of the Common Rule (including requirements of informed consent and prior review by an IRB) only apply to human subjects research, a term that—as defined—excludes research using de-identified samples. *See* 45 C.F.R. § 46.102(f)(2).

378 *See* Joh, *supra* note 132, at 857, 859 n.10.

subject to IRB review; for research that falls outside the purview of the Common Rule and parallel FDA law, third-party review could come from the database in which the genetic material is stored, unless a different IRB is specified. In the criminal justice context, courts should recognize that "abandoned" genetic material is entitled to the same Fourth Amendment protections—namely prior judicial review—that other pieces of crime scene evidence are afforded.

C. *Existing Samples*

The final question that remains concerns the hundreds of millions of genetic samples collected and stored under regimes that did not require consent.[379] Questions about obtaining reconsent for stored samples have long posed vexing. As Alice Hsieh describes:

> Various ethics committees have disagreed as to whether affirmative reconsent should be required for existing samples from other research and diagnostic tests. Principles such as respect for human dignity and the autonomy of the donor seem to demand affirmative re-consent for purposes that were not originally authorized when the sample was taken.[380]

The primary argument in favor of continued use without consent is that the genetic samples are valuable assets that have the potential to advance biomedical knowledge.[381] What the newborn blood spot lawsuits have demonstrated, however, is that regardless of how valuable a collection of genetic data may be, if people perceive that their genetic data is being used without their consent, the continued existence of any biobank could be on shaky legal and ethical footing.

For this reason, this Article proposes that continued use of stored specimens that were collected without consent be subject to a multi-year sunset period, after which specimens obtained without consent can no longer be used. During that multi-year sunset period, the expectation is that biospecimens that were obtained without consent would be rotated out and replaced in storage with specimens that were obtained with

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379 *See* van Diest & Savulescu, *supra* note 39, at 650–51 (noting that it might be challenging to obtain consent for research use of tissues already obtained as part of clinical procedures given the amount of time that may have passed since the materials were collected).

380 Hsieh, *supra* note 16, at 403.

381 *See* Carnahan, *supra* note 44, at 300 ("That newborn bloodspots are a valuable scientific tool, with great potential for the public good, is not disputed. Newborn screening specimens are valuable for medical research that can improve the health of children and provide critical information about the roots of both child and adult diseases."); Suter, *Newborn Screening*, *supra* note 46, at 756 ("[T]hese blood spots, like most pathology samples, are a treasure trove for researchers because they are a valuable national repository of genetic material.").

consent.[382] Use of the samples should also be subject to mandatory third-party review prior to use, an additional protection for individuals unable to protect themselves. This compromise position recognizes the questionable ethics of relying on nonconsensually collected genetic material, but also the hardship that would be imposed by mandating immediate incineration of hundreds of millions of samples.

CONCLUSION

We are at the threshold of realizing the important biomedical advances promised at the beginning of the genetic era. These promised advances rely, in large part, on curating large-scale collections of genetic data. These collections make it possible to identify meaningful associations between genetic variants and disease, with the ultimate goal of developing treatments and interventions for some of the world's most pressing health conditions—cancer, heart disease, autoimmune disorders—targeted at an individual's unique genetic makeup.

The nobility of the goal should not, however, cause us to overlook the questionable ways that genetic material is currently being collected. Under current practice, a range of decisions—including to undergo a blood test at the doctor's office, to enroll a newborn in a public health screening program, to try direct-to-consumer genetic testing, or even to wander through a crime scene—could lead to the collection and storage of individuals' genetic sequences without their knowledge or consent. Once collected, genetic data can be used in research, commercialization, or to identify biologically-linked family members as potential crime suspects, all of which can be carried out with extremely limited third-party review.

The current practice of collecting and using genetic data without consent relies on justifications that do not withstand closer scrutiny. The justifications require accepting that individuals are capable of abandoning their genetic data, that individuals intend to relinquish all interests in their genetic data and voluntarily undertake acts to effectuate that intent; that de-identification procedures adequately protect individuals whose genetic material has been shared; that implementing consent and third-party review would significantly

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382 The Common Rule NPRM proposes to permit continued use of existing samples if identifiers are removed. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 54047 (Sept. 8, 2015). Questions remain about samples that have unique or irreplaceable scientific value. One approach would be to submit requests for continued use to third-party review to ascertain whether there is an adequate scientific justification for continued nonconsensual use.

reduce the number of samples available, despite empirical evidence to the contrary; or that recognizing individuals' ongoing interests in their genetic sequences would impede access to and use of those genetic samples. Each of these justifications falls short.

Accordingly, this Article proposes implementing the longstanding ethical safeguards of informed consent and third-party review that are often discarded in the context of genetic data. Implemented properly—for example, by granting individuals the right to specify the types of subsequent uses for their genetic data—these safeguards promote the ethical collection and use of genetic data and protect against backlash should individuals discover that the current system permits the mass, surreptitious, nonconsensual collection and use of their genetic data. Fostering trust in the collection and use of genetic data is the best defense against potential backlash—backlash that has, in the past, resulted in the destruction of millions of samples thereby potentially impeding important biomedical progress.