

8-2013

## The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?

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### Recommended Citation

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

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# The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?

STEPHANIE A. ALESSI\*

*The field of genetic research has revolutionized modern medicine and will continue to do so in the years to come. For the people whose biological materials form the basis for this research, however, the research process may also lead to personal discoveries—namely, it may expose information about their health, genetic predispositions, and other gene-linked characteristics. Researchers who uncover this kind of personal genetic information are likewise confronted with the question of whether they should—or must—provide their subjects with feedback about their results.*

*For subjects and researchers alike, the answer is unclear. Presently, there is little guidance as to these parties' rights and responsibilities when it comes to the return of genetic results in a research setting. As a result, neither party has a clearly defined understanding of what to expect from the research relationship. This Article draws on recognized ethical and legal foundations to propose that genetic researchers should owe three limited legal duties to their research subjects regarding planning for, acquiring informed consent about, and reporting certain genetic findings. Considering the wide variation among individuals in terms of what genetic information they would like to know, this Article balances concerns for individual autonomy with the right to acquire personal health information, and it weighs those interests against the potential cost to socially beneficial genetic research. In balancing these considerations, this Article's proposals for a limited set of duties offer a careful step toward clearly defining the rights and responsibilities of genetic researchers and their subjects.*

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\* J.D., University of California, Hastings College of Law, 2013; B.A., Stanford University, 2009. Many thanks to Professor Jaime King, whose support and guidance have been invaluable in writing this Article and throughout law school. Thanks also to Dane, Ben, Margot, and the rest of the *Hastings Law Journal* staff for the many hours they have dedicated to making this Volume a success.

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## INTRODUCTION

With the advent of large-scale genetic research, discoveries about the human race that never before seemed possible are becoming a reality. Potentially lifesaving and life-changing concepts that were once elements of science fiction, such as the emerging fields of personalized medicine and pharmacogenomics, are now within reach.<sup>1</sup> To support these scientific discoveries, biobanks catalog library-sized collections of DNA samples and offer researchers access to an increasingly diverse supply of genetic material to use in their research.<sup>2</sup> These stored samples provide the means for studies that will eventually uncover benefits about which we can now only speculate.

Despite the enormous potential of genetic research, the research process itself has potentially troublesome implications for the human subjects who contribute their genetic materials. Chief among these concerns is the question of what to do with the individual data that arise as a result of genetic research. Genetic material may reveal features of a

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1. See, e.g., Francis S. Collins et al., *A Vision for the Future of Genomics Research*, 422 NATURE 835, 843 (2003).

2. See Mark Stranger & Jane Kaye, *Governing Biobanks: An Introduction*, in PRINCIPLES AND PRACTICE IN BIOBANK GOVERNANCE 1, 2 (Jane Kaye & Mark Stranger eds., 2009).

person that she was not even aware existed because a gene typically only becomes visible when it impacts the observable characteristic in one's phenotypic profile. Nonetheless, this genetic information may provide useful insight into one's health status that, if available, many individuals would want to know.<sup>3</sup>

Placing a responsibility on researchers to provide subjects with all theoretically interesting or useful information, however, can detract time and resources from a study's primary purpose. As such, researchers are often forced to balance the subjects' personal interests against their research goals. Yet there exist no uniform standards on which either researchers or subjects may rely as they perform this balancing act. Although researchers are guided by the broad command that, "no matter how important the research questions, it is not ethical to use human participants without appropriate protections,"<sup>4</sup> they have little guidance to help determine what constitute appropriate protections when they must decide whether to return genetic research results. Participants also lack clear guidance as to what information they are entitled to receive.<sup>5</sup> Both parties are thus left with the unanswered question: To what extent is there an ethical obligation, and to what extent should there be a legal duty, to return results to a research subject?

When considering this question, it is crucial to remember that there is wide variation in individuals' expectations about their participation in genetic research.<sup>6</sup> One example that underscores the importance of

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3. See, e.g., Stephanie M. Fullerton et al., *Return of Individual Research Results from Genome-Wide Association Studies: Experience of the Electronic Medical Records and Genomics (eMERGE) Network*, 14 *GENETICS MED.* 424, 425 (2012) ("The rationale for returning such findings is to provide patients with the opportunity for appropriate medical management.")

4. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 851 (Md. 2001) (quoting NAT'L BIOETHICS ADVISORY COMM'N, *ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS* 2–3 (2000) (emphasis omitted) (internal quotation marks omitted)).

5. The line between genetic research and clinical care can often be blurry to research subjects and their families; therefore, simply because information is gathered for research purposes does not relieve researchers of the ethical responsibility to warn them of any negative findings. See D. Pullman & K. Hodgkinson, *Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice*, 69 *CLINICAL GENETICS* 199, 199–200 (2006); see also *infra* Part II.D.

6. See, e.g., Ellen Wright Clayton, *Incidental Findings in Genetic Research Using Archived DNA*, 36 *J.L. MED. & ETHICS* 286, 289 (2008). For example, one particularly complex allele that is associated with heightened cardiovascular risk is also associated with Alzheimer's disease. *Id.* While an individual may want to undergo genetic testing to understand her risk of developing heart disease, she may prefer not to know one way or another about her risk of developing Alzheimer's disease. *Id.*; see also J.S. Roberts et al., *Using Alzheimer's Disease as a Model for Genetic Risk Disclosure: Implications for Personal Genomics*, 80 *CLINICAL GENETICS* 407 (2011) (examining participants' psychological and behavioral responses to learning about their genetic risks of developing Alzheimer's disease). The National Human Genome Research Institute recently awarded \$5.7 million in grants for more data-driven studies of subjects' reactions to finding out results of genetic research. *NHGRI Funds Return of Results Studies, Forms Expert Consortium*, JOHNS HOPKINS BERMAN INST. OF BIOETHICS ANNOUNCEMENTS (Sept. 26, 2011), <http://www.bioethicsbulletin.org/archive/nhgri-funds-return-of-results-studies-forms-expert-consortium>. Ultimately, that funding is designed to help the scientific and

understanding that variation is the story of the Havasupai Tribe.<sup>7</sup> Members of this isolated southwestern Native American tribe submitted blood samples to a genetic researcher for a study on diabetes, but unbeknownst to the tribe members, their blood samples were saved and used in subsequent studies to which they had not intended to consent.<sup>8</sup> These studies uncovered stigmatizing information about the rate of schizophrenia in tribe members and genetic evidence of their evolutionary migration patterns that contradicted the religious folklore about their spiritual origins.<sup>9</sup> Although the researchers, who viewed these studies as socially beneficial, had assumed the tribe members would have no concern about the use of their donated DNA samples for additional research topics beyond diabetes, the tribe members felt it was a fundamental violation of their rights to use their DNA to study topics to which they had not initially agreed.<sup>10</sup>

The case of the Havasupai Tribe illustrates that a subject's autonomy interests do not necessarily align with a researcher's goals. Likewise, for a variety of reasons—spiritual, cultural, personal, or otherwise—individuals may simply not want to know the results that researchers discover about them.<sup>11</sup> The Havasupai case highlights the need to maintain secure protections to ensure that every participant in every study gives appropriate informed consent and is able to opt out of both participating in future studies and receiving any results. Whether or not a researcher agrees with an individual's decision to forego learning about her genetic future, the research design and governance must allow individuals to make such decisions as they see fit.

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legal communities better understand what participants expect when they provide genetic material and thereby help develop a set of best practices with regard to the practical and ethical implications of returning genetic research results. *Id.*

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

8. *Id.* at 1067.

9. *Id.*

10. *Id.* Eventually, Arizona State University “agreed to pay \$700,000 to 41 of the tribe’s members, return the blood samples and provide other forms of assistance to the impoverished Havasupai—a settlement that legal experts said was significant because it implied that the rights of research subjects can be violated when they are not fully informed about how their DNA might be used.” Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES, Apr. 21, 2010, <http://www.nytimes.com/2010/04/22/us/22dna.html>.

11. See, e.g., Barbara Bowles Biesecker et al., *Psychosocial Factors Predicting BRCA1/BRCA2 Testing Decisions in Members of Hereditary Breast and Ovarian Cancer Families*, 93 AM. J. MED. GENETICS 257, 257 (2000) (analyzing the factors influencing the testing decisions of individuals with family histories of breast and ovarian cancer and finding that those who were younger, had optimistic personalities, and belonged to cohesive families were most likely to undergo genetic testing); Kimberley A. Quaid & Michael Morris, *Reluctance to Undergo Predictive Testing: The Case of Huntington Disease*, 45 AM. J. MED. GENETICS 41, 43 (1993) (finding that some individuals who are at risk for Huntington’s disease choose not to undergo predictive testing because of the lack of a cure for the disease, the potential impact on health insurance, the fear of putting their children at risk, and the personal impact of knowing about their impending disease).

Similarly, when developing governance schemes for genetic research, protecting the confidentiality of participants' information must also be a priority. With the threat—or at least the fear of the threat—of genetic discrimination in employment and in the insurance industry,<sup>12</sup> many individuals feel a strong incentive to keep their genetic information private. Any guidelines on this issue must also take account of and protect these privacy interests.

This Article balances three competing goals—promoting socially beneficial genetic research, protecting individual health and access to personal information, and preserving individual autonomy and privacy—and proposes the adoption of specific, limited duties regarding planning for, acquiring informed consent about, and reporting genetic results. These duties must be uniformly and narrowly drawn so as to neither impede scientific progress nor interfere with individuals' rights to their personal autonomy and privacy, but they must also be broad enough to ensure research participants appropriate access to their personal health information. As more people undergo genetic testing, and as the scientific community clarifies more genotype-phenotype links, it will become increasingly common for investigators to uncover genetic findings that have potentially important implications.<sup>13</sup> As such, there is an increasing need to establish a coherent and consistent way to deal with these findings.

This Article attempts to develop a comprehensive set of guidelines on which researchers and participants can steadfastly rely. Part I describes the different contexts in which genetic results can arise and discusses the unique infrastructures in which genetic researchers operate. Parts II and III explore the possible sources of ethical and legal duties as they apply to sharing research results with subjects. Finally, Part IV proposes three specific recommendations of legal duties that researchers should owe to their subjects, taking into consideration the infrastructure and logistics, ethical implications, and legal doctrines relating to genetic research.

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12. See, e.g., Karen H. Rothenberg & Sharon F. Terry, *Before It's Too Late—Addressing Fear of Genetic Information*, 297 *SCIENCE* 196, 196–97 (2002) (“It is only reasonable to be concerned that health insurers and employers may not fully understand the implications and limitations of genetic test results and the complex relationships between genotype and phenotype. . . . [O]nce genetic information enters databases, it will be extremely hard to remove it or prevent disclosure. When the public appreciates the extent of use of genetic information for nonmedical purposes, it will only further exacerbate fear of discrimination and loss of privacy.”); cf. Pullman & Hodgkinson, *supra* note 5, at 202 (“[G]enetic privacy is a somewhat fickle matter, dependent to a large extent on the phenotypic expression of the particular genetic condition. . . . Concerns about insurability can also be misleading, as knowledge of serious genetic disease in the family has to be disclosed, regardless of individual disease status.”).

13. See Isaac S. Kohane et al., *Reestablishing the Researcher-Patient Compact*, 316 *SCIENCE* 836, 836 (2007).

## I. THE CONTEXT

In order to know what society can and should demand of researchers, it is crucial to understand the framework in which they operate. Genetic research can produce results in several different contexts, each of which has unique features that determine what kind of relationship the researcher has with her subjects and what procedures for delivering those results are feasible. It is thus necessary to consider how different types of results might arise within different settings before prescribing across-the-board legal duties. This Part explores three specific points during a study at which researchers should be prepared to address the possibility of finding such results: the institutional review board's evaluation of the study, the potential discovery of incidental findings, and the use of biobanking to store samples.

### A. INSTITUTIONAL REVIEW BOARD OVERSIGHT

The most straightforward way that genetic results may arise is as a product of a study in which the participant knowingly takes part and to which she directly consents. If a study tests for specific genetic links, the research protocol can address which of those results will be shared with the participant and to what extent. Institutional review board ("IRB") oversight standardizes this process. IRBs are formal committees that review and approve research protocols concerning human subjects.<sup>14</sup> They determine whether a proposed study design meets federal standards and is therefore eligible for federal funding and regulatory approval.<sup>15</sup> "An IRB's primary role is to assure the safety of human research subjects,"<sup>16</sup> which means that during the review process the IRB is responsible for addressing any problems with the protocol and ensuring that, before participants contribute any biological materials, they are fully aware of what results they will and will not receive.<sup>17</sup> Knowing what types of results the researchers will produce allows IRBs a full opportunity to consider the financial, physical, and psychological

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14. LORI B. ANDREWS ET AL., *GENETICS: ETHICS, LAW AND POLICY* 94 (3d ed. 2010). The Department of Health and Human Services ("HHS") requires that any institution seeking federal funding for research on human subjects have an IRB review its protocols in accordance with HHS policy. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.122 (2009). To qualify under the regulation, the IRB must have at least five members who are sufficiently qualified and both personally and professionally diverse, including at least one member who is not otherwise affiliated with the institution. *Id.* § 46.107.

15. Henry T. Greely, *The Control of Genetic Research: Involving the "Groups Between"*, 33 *Hous. L. Rev.* 1397, 1401 n.8 (1997).

16. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 814 (Md. 2001).

17. *See id.* at 813 ("Generally, their primary functions are to assess the protocols of the project to determine whether the project itself is appropriate, whether the consent procedures are adequate, whether the methods to be employed meet proper standards, whether reporting requirements are sufficient, and the assessment of various other aspects of a research project.").

burdens of returning results to participants, including concerns about both false positive and false negative reports.<sup>18</sup>

In recognition of the potentially serious implications of returning genetic results, the Department of Health and Human Services' Office for Human Research Protections has issued a guidebook that requires IRBs to make sure that research protocols minimize harm by providing for genetic counseling any time a researcher delivers genetic information.<sup>19</sup> This requirement reflects the judgment that merely disclosing findings may not sufficiently ensure that an individual completely understands the implications of a genetic diagnosis.<sup>20</sup> Researchers, after all, are often not medically trained and therefore may not be skilled in effectively communicating serious clinical information.<sup>21</sup> By contrast, genetic counselors are specifically trained to interpret genetic and medical information and to convey that information to patients in a way that helps them understand and respond to genetic risks.<sup>22</sup> During review, the IRB can ensure that the study protocol has a plan in place to refer participants for genetic counseling that is tailored to the kind of information the investigators foresee finding in the course of the study.

Despite this requirement, however, current IRB regulations do not thoroughly reflect the present state of genetic technology. The regulations leave too much room for variation in how researchers decide which results to return.<sup>23</sup> If researchers' and participants' expectations about studies are to be nationally uniform, there must be additional standards to specify how these issues should be addressed so as to promote the development of widespread reliance on, and trust in, genetic research.<sup>24</sup>

## B. INCIDENTAL FINDINGS

Planning for results becomes increasingly difficult when the results cannot be predicted, as is the case with incidental findings. An incidental finding is "a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the

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18. Susan M. Wolf et al., *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361, 366–67 (2008).

19. *Id.* at 367; see IRB GUIDEBOOK, OFFICE FOR HUMAN RESEARCH PROTECTIONS (2003), available at [http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm) (overseeing the rights and wellbeing of human subjects in HHS-supported research).

20. Moira A. Keane, *Institutional Review Board Approaches to the Incidental Findings Problem*, 36 J.L. MED. & ETHICS 352, 355 (2008).

21. *Id.* at 354.

22. *FAQs About Genetic Counselors and the NSGC*, NAT'L SOC'Y OF GENETIC COUNSELORS, <http://www.nsgc.org/About/FAQsaboutGeneticCounselorsandtheNSGC/tabid/143/Default.aspx> (last visited July 30, 2013).

23. Keane, *supra* note 20, at 352–53.

24. *See id.*

course of conducting research but is beyond the aims of the study.”<sup>25</sup> For example, testing a multi-functional gene for its role in one disease might indicate unexpected results about a different disease or condition.<sup>26</sup> Similarly, a study of the genetic aspects of a certain disease might inadvertently reveal that a nearby gene—not included in the study but close enough that the researcher might notice—has a potentially dangerous mutation.<sup>27</sup> Incidental findings occur frequently, and as routine whole genome sequencing becomes increasingly common, the potential to find incidental results will only continue to grow.<sup>28</sup>

Incidental findings in the genetic context can range in severity, including anything from a serious health problem to a misattribution of paternity.<sup>29</sup> Because different types of findings will have different physical, psychological, and sociological implications, standardizing treatment of these findings is challenging.<sup>30</sup> Therefore, the factors that researchers use to decide which incidental findings to return must be able to account for these variations.

There is no current consensus, however, as to what those factors are, which makes it difficult for both the researchers and the reviewing IRBs to address the problem of incidental findings in their research protocols.<sup>31</sup> Furthermore, IRBs must consider whether some results might cause more harm than benefit to the subject if they are disclosed. For instance,

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

26. Clayton, *supra* note 6, at 289.

27. *Id.* at 288.

28. Mildred K. Cho, *Understanding Incidental Findings in the Context of Genetics and Genomics*, 36 J.L. MED. & ETHICS 280, 281 (2008); Ma'n H. Zawati & Amélie Rioux, *Biobanks and the Return of Research Results: Out with the Old and In with the New?*, 39 J.L. MED. & ETHICS 614, 616 (2011). Cho cites improvements in genetic research data and its availability to a wide range of researchers, as well as the increasingly clear links between genetics and medicine, as some of the primary factors behind this growth. Cho, *supra*, at 281.

29. Wolf et al., *supra* note 18, at 362 (“Genetic family studies are estimated to reveal misattributed paternity in about 10 percent of research participants in the general population.”); see Clayton, *supra* note 6, at 288 (“By far the most common incidental finding in genetics is misattributed paternity, which is typically estimated to occur in 1–10 percent of pregnancies.”).

30. Clayton, *supra* note 6, at 290.

31. Keane, *supra* note 20, at 353; Wolf et al., *supra* note 18, at 362. Recently, the American College of Medical Genetics and Genomics released a report recommending how to approach incidental findings in the context of clinical genome sequencing. ROBERT C. GREEN ET AL., AM. COLL. OF MED. GENETICS & GENOMICS, *ACMG RECOMMENDATION FOR REPORTING OF INCIDENTAL FINDINGS IN CLINICAL EXOME AND GENOME SEQUENCING* (2013). The report specifies a list of serious gene-linked diseases for which “prevalence may be high and intervention may be possible” and states that, for findings related to these particular conditions, the duty to warn patients “supersedes concerns about autonomy.” *Id.* at 11. In addition to recognizing the ethical concerns regarding this potential violation of the “right not to know,” *id.*, the report also notes that “there are insufficient data on clinical utility to fully support these recommendations” and calls for ongoing updates thereto. *Id.* at 3. Though imperfect, this sort of analysis can be useful in developing and improving the approach to incidental findings in the research setting.

informing a subject of a genetic abnormality that either has unclear health implications or lacks any available treatment could cause significant psychological distress.<sup>32</sup> Returning ambiguous genetic findings, especially outside of the clinical setting, may cause unnecessary alarm, in some cases leaving the individual worse off than if she had been told nothing.<sup>33</sup> Nonetheless, although it is “impossible to anticipate everything that might be discovered,” as the scientific community’s understanding of genetics improves, it will be possible to more readily distinguish between serious diseases and minor genetic risks.<sup>34</sup> Researchers should therefore be prepared to consider these distinctions and plan how they will make these determinations.

### C. BIOBANKS

The practice of biobanking further complicates the problem of returning the results of genetic research. Biobanks establish an infrastructure upon which genetic researchers can conduct unspecified future research.<sup>35</sup> They gather and warehouse blood samples either by donation<sup>36</sup> or, in some cases, by collection of discarded clinical samples.<sup>37</sup> By receiving, storing, and providing biological materials, biobanks furnish researchers with a supply of genetic information that they can use

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32. Keane, *supra* note 20, at 353. It is common for individuals who are at risk for certain chronic illnesses to forego predictive testing due to the psychological implications of knowing that one is living with an incurable disease. *See, e.g.*, Biesecker et al., *supra* note 11 (breast cancer); Quaid & Morris, *supra* note 11 (Huntington’s disease); Roberts et al., *supra* note 6 (Alzheimer’s disease).

33. Wolf et al., *supra* note 18, at 364; *see also* U.K. BIOBANK, ETHICS AND GOVERNANCE FRAMEWORK VERSION 3.0, at 7 (2007), available at <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> (“[T]he value of such feedback is questionable because the data would be communicated outside of a clinical setting and would not have been evaluated in the context of the full medical record. . . . Further, it is not likely to be constructive, and might even be harmful (including causing undue alarm and having potentially adverse effects on insurance and employment status), to provide information without prior counseling or support.”).

34. Clayton, *supra* note 6, at 290. For example, repeated studies of specific genes are likely to give rise to findings that become more predictable over time and with research experience. Cho, *supra* note 28, at 282. In contrast, incidental findings are more difficult to anticipate in non-specific, exploratory genetic research. *Id.* at 281–82.

35. Zawati & Rioux, *supra* note 28, at 615.

36. Individuals sometimes provide materials “specifically for research purposes.” Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 100 (2010). Notably, however, at least one court has found that those who donate their biological materials have no right to determine how the biobank uses those materials. *Id.* at 101–02 (citing Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006)).

37. *Id.* at 100 (“Stored biological materials come from a variety of sources, such as newborn blood spots taken for screening purposes [and] blood, tissues, and other materials taken for clinical diagnostic purposes . . .”); *see* D.M. Roden et al., *Development of a Large-Scale De-Identified DNA Biobank to Enable Personalized Medicine*, 84 CLINICAL PHARMACOLOGY & THERAPEUTICS 362, 362 (2008) (describing the “opt-out” system for amassing discarded, de-identified blood samples initially collected for clinical purposes at Vanderbilt University Medical Center).

to conduct broad, population-based studies.<sup>38</sup> Ultimately, the goal of biobanking is to supply enough biological information so that scientists can analyze links between genotypes and phenotypes, determine the causes of common tendencies across a population, and develop tools to apply those results generally to medicine.<sup>39</sup> By design, biobanks aim to help society rather than individual donors, a structure that encourages little institutionalized concern for the individual biobank depositor. As a result, despite the many societal benefits of biobanking, the policies of biobanks often do not account for individuals' concerns about accessing their results.

When they communicate test results, genetic researchers may choose to give feedback in a variety of ways: initial lab analysis and feedback, aggregate results from the study, and individual results after the research is completed.<sup>40</sup> Typically, as long as the participant consents to finding out her results, the initial feedback can be provided to her or her physician immediately at the time of donation to the biobank.<sup>41</sup> But the aggregate and individual research results of studies on biobanked materials pose a similar problem to that of incidental findings: It is not feasible to account for all potential future research at the moment the individual first contributes her DNA. In determining whether to return these results, researchers who rely on biobanks for their biological materials must weigh whether to alert the entire research cohort and risk scaring people with potential false positives or to re-identify individuals and only present specific participants with their findings.<sup>42</sup> In some cases, it may be possible to do both by sending an update to all donors about general findings and then providing individualized information where it is warranted.<sup>43</sup> However, individual follow-up without the guidance of a genetic counselor can be inadequate and psychologically risky, especially if the donor made her initial contribution to the biobank in the distant past and does not expect to receive any feedback.<sup>44</sup>

Researchers can use the informed consent process to alleviate some of the psychological risks of returning unexpected genetic findings. One solution is to obtain informed consent at the beginning of every study by

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38. Zawati & Rioux, *supra* note 28, at 615.

39. Roden et al., *supra* note 37, at 365. Public support is crucial for biobanks, "as it is only with continued donation of samples and data, and large-scale investment programmes that genomic research will continue." Stranger & Kaye, *supra* note 2, at 2.

40. Zawati & Rioux, *supra* note 28, at 615.

41. *Id.*

42. Kohane et al., *supra* note 13, at 836.

43. See Zawati & Rioux, *supra* note 28, at 615-16. Many biobanks, for instance, send regular newsletters to biobank contributors with information about the latest research on their biological materials. *Id.*

44. See Clayton, *supra* note 6, at 286-87.

re-contacting donors and allowing them to opt out.<sup>45</sup> Others argue that general informed consent to all future research is sufficient and avoids the administrative hurdles involved in re-contacting every donor.<sup>46</sup> However, if this general informed consent does not fully disclose all of the actual risks and benefits of contributing genetic information to a biobank—namely, those associated with having one’s materials used in unspecified studies and finding out (or not finding out) the results—it may, like in the case of the Havasupai Tribe, not truly reflect the participants’ choices and thus invalidate their consent.<sup>47</sup> Because the protocols for future research projects have not yet been designed, a donor cannot fully understand the benefits and risks of agreeing to take part in subsequent studies at the time of donation.<sup>48</sup> Thus, if the informed consent process is not carefully designed and reviewed, it may leave unresolved many of the psychological risks that go along with returning results to biobank contributors.

Further complicating the problem of returning results is the de-identification of biological materials stored in biobanks. Biological materials are typically stripped of the donor’s identifying information and stored with a code that can connect the material back to her in the future. “The value of the biobank,” after all, “is largely contingent upon being able to link the samples with donor information and its value increases with the depth and quality of the information.”<sup>49</sup> Although it may prove difficult to return results where the data are de-identified and stored over a long period of time (largely due to the associated administrative barriers),<sup>50</sup> a significant number of people are comfortable with researchers using their de-identified genetic information so long as they are notified in advance and are given the opportunity to consent or refuse.<sup>51</sup> Proponents argue that this kind of advance-consent procedure could benefit society immensely. Such a procedure could increase donations of materials to the biobank and thereby allow the study of many different phenotype-allele connections without creating any

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45. *Id.*

46. See Lukas Gundermann & Ulrich Stockter, *Co-Determination of Donors in Biobanks*, in *PRINCIPLES AND PRACTICE IN BIOBANK GOVERNANCE*, *supra* note 2, at 69, 71 (“[T]he general need for explicit informed consent can be abandoned if a substantial public interest so requires. . . . It also justifies a reduced standard of informed consent, for example, allowing for a one-time broad consent plus additional elements that safeguard autonomy.”).

47. See *supra* notes 6–11 and accompanying text. This may undermine not only the participants’ rights but also the development of the biobank and the research conducted on the materials stored in it.

48. Clayton, *supra* note 6, at 287.

49. Stranger & Kaye, *supra* note 2, at 2.

50. Fullerton et al., *supra* note 3, at 429.

51. Roden et al., *supra* note 37, at 363. In response to a survey of clinical research patients, 90% were “comfortable with the idea of anonymized genetic information being used for research,” and 5% were opposed. *Id.* When given fully informed consent, including a description of the DNA databank, and allowed to opt out of having their materials included by checking a box, roughly 2.5% of patients did so. *Id.*

serious risks of discrimination or breach of privacy due to the anonymity of the data.<sup>52</sup>

In recognition of the ethical and logistic dilemmas that arise from the return of individual results, many biobanks explicitly prohibit returning any such results and inform research participants of this prohibition upon the initial submission of their biological materials.<sup>53</sup> For instance, CARTaGENE, the Université de Montréal's biobank, specifies that "[n]o results from future research projects using data or samples will be communicated to participants."<sup>54</sup> Other institutions take the same approach but recognize caveats under which they will disclose information if it is reasonably clear that the benefits of doing so outweigh any risks to the individuals or their families.<sup>55</sup>

Although many biobanks are already considering how different factors affect their decisions about returning research results to individuals, there is no standardized way that they make this determination. To create a clear set of rules upon which researchers and potential donors may rely, it is necessary to consider how established ethical principles and legal regimes prescribe the treatment of these kinds of problems. The following two Parts examine the relevant ethical and legal foundations, respectively, in which such rules may be grounded.

## II. ETHICAL FOUNDATIONS

Reflected in national and international guidelines, as well as our understanding of individual rights, certain ethical principles are consistently recognized throughout U.S. law and policy. These principles should shape genetic researchers' legal obligations to their subjects, irrespective of the specific legal regime in which those obligations may be grounded. Because genetic research operates within an emerging and sparsely developed area of the law, these ethical foundations provide crucial guidance in developing appropriate and principled duties. This Part describes the origins of these ethical standards.

### A. NATIONAL PRINCIPLES

In the late 1970s, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research delineated a set of ethical principles for human subjects research in the Belmont Report.<sup>56</sup>

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52. *Id.* at 365.

53. Zawati & Rioux, *supra* note 28, at 616–17.

54. CARTaGENE, UNIVERSITÉ DE MONTRÉAL, INFORMATION BROCHURE FOR PARTICIPANTS 10.

55. See, e.g., ALSPAC ETHICS & LAW COMM., UNIV. OF BRISTOL, POLICY GUIDANCE REGARDING DIVULGING BIOMEDICAL INFORMATION TO PARTICIPANTS (2010).

56. U.S. DEP'T OF HEALTH & HUMAN SERVS., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter THE BELMONT REPORT], available at <http://www.hhs.gov/ohrp/policy/belmont.html>. The 1974 signing of the National

The Belmont Report is simply a policy statement, but it lays out the basic ethical guidelines for human subjects research and prescribes how those principles should be applied.<sup>57</sup>

The Belmont Report sets out two general rules that should underlie all research: “(1) do not harm and (2) maximize possible benefits and minimize possible harms.”<sup>58</sup> These rules are at the core of the Belmont Report’s discussion of how to deal with returning research results:

In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them.<sup>59</sup>

Though written years before genetic research was commonplace, this language implies that researchers are obliged to provide their human research subjects with fully informed consent and to decide in advance how they will deal with returning genetic research results. At the same time, it recognizes that disclosure may be limited if it would impede the aims of the research. Part IV discusses these conclusions in greater detail,<sup>60</sup> but it is clear that the Belmont Report contemplates some measure of ethical duty for researchers to report results.

#### B. INTERNATIONAL PRINCIPLES

In addition to recognizing the importance of protecting human research subjects at a national level, the United States has signed on to globally recognized declarations asserting and preserving the right to human dignity in research. The Nuremberg Code, drafted in the wake of horrific and tragic human experimentation during World War II, asserts ten principles of human subjects research.<sup>61</sup> The Nuremberg Code specifies that research on humans must “avoid all unnecessary physical and mental suffering and injury,”<sup>62</sup> which suggests that the psychological health of human research subjects should be a primary concern when researchers are crafting a protocol for returning results.

Building upon the Nuremberg Code, the Declaration of Helsinki announced the World Medical Association’s Ethical Principles for Medical

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Research Act created this commission and charged it with developing ethical guidelines to underline research on human subjects. *Id.*

57. *Id.*

58. *Id.* at B.2.

59. *Id.* at C.1 (emphasis omitted).

60. *See infra* Part IV.

61. *Nuremberg Code: Directives for Human Experimentation*, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181-82 (1949), available at <http://www.hhs.gov/ohrp/archive/nurcode.html>.

62. *Id.* at no. 4.

Research Involving Human Subjects.<sup>63</sup> The Declaration of Helsinki, first adopted in 1964 and amended several times since, proclaims that “the well-being of the individual research subject must take precedence over all other interests.”<sup>64</sup> The World Medical Association thus placed an affirmative, global priority on protecting human research subjects—even if at the expense of scientific discovery—and informed the researcher that she should always place her subjects’ well-being above the success of her research.

These treaties, however, do not address and did not contemplate the intricacies of genetic research. Where it is unclear whether returning or not returning results will be more problematic, and where results may only be marginally useful to a subject as compared to the burden on the researcher, the treaties do not give a clear ethical answer. Rather, the researcher must weigh the specifics of the situation to decide what is in the best interest of her subjects.

### C. RIGHT TO PERSONAL INFORMATION

Aside from formal declarations of the rights of human subjects, human beings have an interest in accessing their own personal health information.<sup>65</sup> Although courts have held that an individual does not have a right of ownership in her cells,<sup>66</sup> the same logic does not apply to one’s personal genetic information that may have potential health or reproductive consequences.<sup>67</sup> For example, Congress recognized the right to one’s health information when it passed the Health Insurance Portability and Accountability Act (“HIPAA”).<sup>68</sup> HIPAA gives individuals a right to access their personal health information, but in order to exercise that right, one must actively request the information.<sup>69</sup> The obvious problem in applying HIPAA’s logic to genetic research results is that, where the results indicate the presence of a disease that may not be physically apparent, the individual may not have any idea what results exist about her and therefore cannot know to ask for them. Thus, imposing an affirmative duty on researchers to report results seems to be the only way to truly give individuals the informational access that they deserve.

If applied too broadly, however, this proprietary interest could be problematic. A right to all genetic information could impose on

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63. World Med. Ass’n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (2008), available at <http://www.wma.net/en/30publications/10policies/b3>.

64. *Id.* at no. 6.

65. See Wolf et al., *supra* note 18, at 372.

66. See, e.g., Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 489 (Cal. 1990).

67. See Wolf et al., *supra* note 18, at 372.

68. See Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936 (1996).

69. *Id.* § 1175; see Wolf et al., *supra* note 18, at 365.

researchers an enormous burden to look for information that is entirely beyond the aims of the study, which could undermine their research efforts.<sup>70</sup> But if information relevant to a subject's health is discovered in the ordinary course of research, there is a strong ethical argument that the individual is entitled to that information because providing access to personal information would not impose a substantial burden on the researcher.

#### D. THERAPEUTIC MISCONCEPTION

The therapeutic misconception is another ground that supports an ethical duty to report results. When dealing with cases about human subjects research, courts have relied on this theory to support their findings of legal duties.<sup>71</sup> The therapeutic misconception arises out of the trust that research participants place in the researcher and reflects a belief that participation in the research will provide them with a clinical benefit.<sup>72</sup> Even if a subject purports to understand that there is no clinical relationship, her decision to permit the researcher to study her DNA may lead to an erroneous belief that any and all clinical results will be returned.<sup>73</sup>

For example, when one woman who had been diagnosed with breast cancer encouraged her two sisters to take part in a university research study on the hereditary breast cancer gene *BRCA1*, they were told that their results were inconclusive, "received no regular status updates and, when [they] called . . . , [their] inquiries were met with annoyance."<sup>74</sup> After three years of uncertainty, never knowing if or when the researchers would contact them, the woman's two sisters both underwent preventative mastectomies—only to find out later that they did not have

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70. Wolf et al., *supra* note 18, at 376.

71. See *infra* notes 102–112 and accompanying text.

72. Wolf et al., *supra* note 18, at 365–66. The therapeutic misconception was first identified during a psychiatric study in which it became clear that many of the subjects, despite having been told that their treatments were randomized, believed that they were assigned to the treatments that were best for their individual problems. Paul S. Appelbaum et al., *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, 5 INT'L J.L. & PSYCHIATRY 319, 319–23 (1982).

73. Wolf et al., *supra* note 18, at 365–66. In fMRI studies, for example, despite the lack of any physician-patient relationship, researchers have a general responsibility to do a diagnostic reading and follow up on any questionable results, largely in recognition of the participants' reliance interests. *Id.* However, even when there is no such responsibility, it can be difficult for participants to understand the meaning of complicated informed consent documents, especially if, as is often true of individuals who are suffering from a serious illness, they are prone to "filter information [out] of their own sense of desperation." Lisa M. Arkin et al., *Confronting the Issues of Therapeutic Misconception, Enrollment Decisions, and Personal Motives in Genetic Medicine-Based Clinical Research Studies for Fatal Disorders*, 16 HUM. GENE THERAPY 1028, 1029 (2005).

74. Rebecca Fisher, *A Closer Look Revisited: Are We Subjects or Are We Donors?*, 14 GENETICS MED. 458, 458 (2012).

the breast cancer gene and that the surgeries had been unnecessary.<sup>75</sup> Although the sisters expected their participation “to deliver actionable results specifically to [them],” the researchers viewed them “as only one set of data points among many.”<sup>76</sup> As a result, the three sisters came away from the experience feeling a “profound sense of betrayal” and lost confidence in the medical profession.<sup>77</sup> Even though the sisters had participated in the research to contribute to the growth of knowledge about the BRCA1 allele and seemed to understand the study’s population-based goals, they nonetheless felt entitled to some level of clinical care with regard to their genetic information.<sup>78</sup>

Because a research participant’s reliance interest can be significant, informed consent material may not be sufficient to clearly establish the researcher’s responsibilities and manage participants’ expectations.<sup>79</sup> It is human nature to rely on a person of greater knowledge and access to one’s health information and to expect disclosure if that information has negative implications. While a researcher may view the individual’s results as nothing more than a data point, to the participant they are infinitely more personal and meaningful. Consequently, even if an informed consent document specifies that participants should not expect to get any individual results back, a practical perspective with a focus on the social values of fairness and reciprocity suggests that they should be entitled to something more consistent and thorough than what they currently receive.

If not done carefully, however, returning results may further encourage the therapeutic misconception by familiarizing research participants with the notion that researchers will provide them with all clinically relevant genetic information, whether related to the study or not.<sup>80</sup> In reaction to this concern, some biobanks have already made efforts to limit their liability by including procedures about how to provide individual feedback and what caveats to include in order to keep research subjects from thinking that “the assessment is equivalent to a medical check-up.”<sup>81</sup> Otherwise, an individual subject might misinterpret the goal of the research and where the project’s priorities lie—that is, in the population rather than the individual. The potential for misunderstanding makes it imperative that any legal duty to report

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75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *See id.*

80. Wolf et al., *supra* note 18, at 364. It is for this reason that many researchers expressly include a notice at the informed consent stage that they will not return any results. *Id.* In addition, because of the unclear guidance as to how much information to share, there remains the constant possibility of causing emotional distress by reporting too much. *Id.*

81. Zawati & Rioux, *supra* note 28, at 615.

results be narrowly drawn so as not to place a burden on researchers that will only undermine the research it aims to promote.

### III. SOURCES OF LEGAL DUTY

While no single U.S. law delineates researchers' duties to return genetic results, there exists a strong legal background from which it is possible to develop appropriate duties. U.S. regulations and common law alike support some measure of a legal duty owed by researchers to their subjects. By examining the established jurisprudence as it relates to genetic researchers—together with the ethical principles described in Part II—it becomes possible to determine what types of legal obligations are feasible extensions of existing law.

#### A. REGULATORY LAW: THE COMMON RULE

The U.S. Federal Policy on the Protection of Human Subjects—known as the Common Rule—establishes the protection of human subjects as a national priority.<sup>82</sup> Numerous federal agencies, including the Department of Health and Human Services (“HHS”),<sup>83</sup> have codified the Common Rule in their regulations.<sup>84</sup> The Basic HHS Policy for Protection of Human Research Subjects mandates that IRBs approve human subjects research only if the participants' risks are minimized<sup>85</sup> and “reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”<sup>86</sup> It also requires an informed consent process characterized by a clear description of risks, benefits, and alternatives, as well as information about whom to contact if the subject has questions and an acknowledgement of the right to refuse or discontinue one's participation in the research.<sup>87</sup> “[W]hen appropriate,” the IRB may provide additional informed consent elements, including an agreement that the participant has a right to receive any future significant findings resulting from her participation in the research.<sup>88</sup> In addition, the HHS

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82. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited July 30, 2013).

83. See Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. §§ 46.100–.124 (2009).

84. *Id.*

85. *Id.* § 46.111(a)(1). Risks are minimized when the protocol uses procedures that are “consistent with sound research design” and, if possible, are already being used “for diagnostic or treatment purposes.” *Id.*

86. *Id.* § 46.111(a)(2). “The IRB,” however, “should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.” *Id.*

87. *Id.* § 46.116(a).

88. *Id.* § 46.116(b).

Policy provides that a participant cannot waive any of her legal rights or release the researcher or institution from liability for negligence.<sup>89</sup>

Despite this powerful regulatory language, which recognizes an individual subject's right to protect herself when taking part in human subjects research, the Common Rule does not encompass a private cause of action, and no court to date has recognized such a right.<sup>90</sup> Consequently, an individual who suffers harm as a result of a genetic researcher's negligence in either returning or failing to return her results must find a cause of action beyond the Common Rule if she is to receive any court-sanctioned remedy for her injury.

#### B. COMMON LAW: SPECIAL RELATIONSHIP

At common law, researchers' duties to the participants in their studies have traditionally been limited.<sup>91</sup> Unlike in the medical context, in a non-clinical research setting there is no physician-patient relationship that easily establishes a duty to the research participant. Without such a duty, there is no legal requirement that the researcher take any affirmative steps to report results to a participant, so it is necessary to understand the extent to which the common law supports a duty from researcher to subject. While there may be other ways to establish these duties, this Subpart describes in detail the obligations that arise out of the special relationship between the researcher and the participant.

When a physician conducts research in a clinical setting, the common law imposes certain duties on the patient based on the physician-patient relationship.<sup>92</sup> Those same duties, however, do not necessarily apply where a researcher lacks a therapeutic relationship with the participant.<sup>93</sup> A duty that goes too far in a purely research context could chill socially beneficial research and allow subjects control over the direction of research in which they are not otherwise invested.<sup>94</sup>

Despite these concerns, and despite the limited case law dealing with researcher-participant disputes, one court has found that, under the

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89. *Id.* § 46.116.

90. Wolf et al., *supra* note 18, at 368.

91. See generally Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking About the Clinical Care that Researchers Owe Their Subjects*, 34 HASTINGS CTR. REP. 25 (2004) (describing the relationship between a researcher and her subject as creating a duty less than what a physician owes her patient but greater than the bounds of the research protocol).

92. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (holding that a physician has a duty to disclose personal, non-health-related interests that may materially affect her medical judgment).

93. *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003) (declining to extend the duty to disclose economic interests where a researcher is not in a therapeutic relationship with the patient). The court in *Greenberg* found that *Moore* was "clearly distinguishable" because of this lack of clinical dependence. *Id.*

94. *Id.* at 1070-71.

right circumstances, a researcher may have a legal duty to report individual results to participants in her research.<sup>95</sup> *Grimes v. Kennedy Krieger Institute* involved a study on lead paint abatement in which investigators collected blood samples from children and dust samples from their homes in order to compare the changing levels of lead over a two-year period.<sup>96</sup> Although the protocol did not contain any affirmative requirement that the research institute report results to the study participants, the parents were dismayed to discover that the researchers had not disclosed evidence that their children's blood samples indicated they were suffering from lead poisoning.<sup>97</sup> The court sided with the parents, holding that even when a clinical relationship is lacking, a special relationship can exist between a researcher and her subject that is sufficient to give rise to a duty to report individual results.<sup>98</sup> Whether such a relationship exists, the court noted, is a question of fact to be made on a case-by-case basis.<sup>99</sup>

Although the study in *Grimes* represents a somewhat different situation from genetic testing, the court's analysis provides useful insight into the kinds of relationships that can trigger a duty of care. Notably, because the risk in *Grimes* was environmental rather than genetic, had the subjects been warned of the lead poisoning, it would have been possible for them to escape their peril by moving elsewhere.<sup>100</sup> In addition, the researchers in *Grimes* encouraged many of the families in the study to live in homes where there was a known likelihood of risk.<sup>101</sup> In genetic testing, on the other hand, the results are often much less clear and the solutions less straightforward. Nonetheless, the relationships between researchers and subjects in both cases are analogous, so the analysis of the relationship in *Grimes* provides a worthwhile comparison.

The *Grimes* court relied on two underlying theories to justify its result: the misalignment of interests between researchers and subjects and the knowledge gap between the two parties.<sup>102</sup> Medical researchers, like physicians, have information about their subjects that the subjects likely do not know. Unlike physicians, however, researchers respond to

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95. See generally *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

96. *Id.* at 822.

97. *Id.* at 824–29.

98. *Id.* at 846. The court also described the relationship as arising from the contractual agreement between the parties, which is a viable legal avenue but is outside the scope of this Subpart. See *id.* at 843–44.

99. *Id.* at 858 (“[U]nder certain circumstances, such research agreements can, as a matter of law, constitute “special relationships” giving rise to duties, out of the breach of which negligence actions may arise. We also hold that, normally, such special relationships are created between researchers and the human subjects used by the researchers. Additionally, we hold that governmental regulations can create duties on the part of researchers towards human subjects out of which “special relationships” can arise. Likewise, such duties and relationships are consistent with the provisions of the Nuremberg Code.”).

100. See *id.* at 812.

101. *Id.*

102. *Id.* at 837–51.

incentives that concern society as a whole rather than individual patients; thus, researchers lack an incentive to disclose individual results.<sup>103</sup> Although a study may benefit society's greater good and a researcher may have only the best intentions, her interests are not aligned with those of the individual research participant, who "stands to gain nothing and lose everything, including his or her right of self-determination."<sup>104</sup>

Likewise, when researchers know more about the participants' health than the participants themselves do, the participants "cannot and should not be solely responsible for their own protection."<sup>105</sup> Rather, where the information and interests are so misaligned as they are in cases like *Grimes*, the nature of the relationship between the two demands that the researcher be legally obligated to act in the participant's best interest.<sup>106</sup> In genetic research, the gap between what researchers and their subjects know is often even greater because genetic information can be uniquely difficult for laypersons to assess—a fact that strengthens *Grimes*' reasoning were it to be applied in a similar case in the context of genetic research.

The *Grimes* court also noted that IRB approval of an informed consent protocol cannot extinguish a researcher's legal duty,<sup>107</sup> which makes it crucial to understand prior to a study exactly what duties researchers owe human subjects. Particularly when genetic information is involved, some commentators view the informed consent process itself—and the consequent entrusting of one's rights in another person—as the crux of the broader rule that the *Grimes* court articulated.<sup>108</sup> "Having gotten the participants to waive their rights against such access to private aspects of their bodies," they argue, "the researchers obtain special responsibilities to look after the fundamental values that those rights normally protect."<sup>109</sup> That is, when a subject provides a researcher access into the privacy of her body and medical history, the researcher must take over the responsibility of dealing with any threats revealed in the course of exercising that privileged information.<sup>110</sup> This partial

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103. *Id.* at 838.

104. *Id.* at 837 (quoting Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157 (1998)) (internal quotation marks omitted); see also *Havasupai Tribe v. Ariz. Bd. of Regents*, 204 P.3d 1063, 1066–67 (Ariz. Ct. App. 2008) (recognizing the inherent misunderstanding between researchers, who saw their research as beneficial for all of society, and their subjects, who were nonetheless morally and religiously opposed to further research).

105. *Grimes*, 782 A.2d at 851 (quoting NAT'L BIOETHICS ADVISORY COMM'N, *ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS* 3–4 (2000)) (internal quotation marks omitted).

106. *See id.*

107. *Id.* at 850–51 ("The duty to a vulnerable research subject is independent of consent, although the obtaining of consent is one of the duties a researcher must perform.")

108. See Henry S. Richardson & Mildred K. Cho, *Secondary Researchers' Duties to Return Incidental Findings and Individual Research Results: A Partial-Entrustment Account*, 14 GENETICS MED. 467, 470 (2012).

109. *Id.*

110. *Id.*

entrustment theory, rather than focusing on ethical values like respect and reciprocity that may not as readily attach in the case of secondary research and biobanks,<sup>111</sup> emphasizes that a duty arises the moment an individual puts her trust in somebody else who is prepared to accept that commitment.<sup>112</sup> Under this logic, it may not even be necessary that the research participant ever meet the researcher, much less form a personal bond, only that she establish a special relationship by entrusting the researcher with her DNA and ensuring that the researcher accept that responsibility.

Establishing a special relationship may also give rise to a duty to warn. A duty to warn may arise if an individual has information that, if disclosed, can help avoid a serious, foreseeable harm.<sup>113</sup> In the context of research, such a duty may exist if there is “unequal knowledge and the defendant possessed of such knowledge, knows or should know that harm might occur if no warning is given.”<sup>114</sup> Courts in duty to warn cases focus on the notion that one person should not withhold information from another when that information could protect the second individual from serious harm and when there is no significant cost to share it.<sup>115</sup> For instance, if a researcher gets samples from a biobank and discovers that an individual research subject has a high chance of developing a deadly illness that can be prevented if treated early, the holder of the information (the researcher) faces little burden in warning the participant of a preventable disease that otherwise might kill her. In such a case, although some critics argue otherwise,<sup>116</sup> there need not be any

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111. *See id.* at 468–69.

112. *See id.* at 470.

113. *See, e.g.,* Tarasoff v. Regents of Univ. of Cal., 551 P.2d 334, 344–45 (Cal. 1976).

114. Wolf et al., *supra* note 18, at 370 (quoting *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 805 (N.D. Ill. 1999)) (internal quotation marks omitted). In *Blaz v. Michael Reese Hospital Foundation*, the court denied the defendant physician’s motion to dismiss when a former patient who had undergone radiation therapy as a child sued, arguing that the physician failed to adequately disclose the results of his subsequent research and warn the plaintiff of the risks of developing neural tumors. 74 F. Supp. 2d at 804, 807. The court cited four criteria established by the Illinois Supreme Court as those giving rise to a duty to warn: (1) the foreseeability of the harm, (2) the likelihood of the injury, (3) the weight of the burden of warning the plaintiff, and (4) the effect of that burden on the defendant. *Id.* at 805. *Blaz*, however, differs from the genetic research setting because the physician in that case directly caused the physical risk to the patient, rather than simply discovering a preexisting risk, making the consequences of placing the burden of warning the plaintiff different in the two scenarios. *See id.* at 806.

115. Wolf et al., *supra* note 18, at 371.

116. *See* Loane Skene, *Feeding Back Significant Findings to Participants and Relatives*, in PRINCIPLES AND PRACTICE IN BIOBANK GOVERNANCE, *supra* note 2, at 161, 169. Critics also suggest that there is a causation problem inherent in this argument because the researcher does not actually cause the harm—that is, the genetic disorder—to the participant. *Id.* However, applying the loss of chance doctrine is helpful in these cases in allowing us to think of the harm suffered as the loss of a chance to get early, appropriate medical care. *See* Wolf et al., *supra* note 18, at 371; *see also* *Herskovits v. Grp. Health Coop. of Puget Sound*, 664 P.2d 474, 476 (Wash. 1983) (“Some courts . . . have allowed the proximate cause issue [of whether a defendant increased the decedent’s risk of death by decreasing the

direct relationship between the researcher and the subject for the duty to apply<sup>117</sup> because it depends not on a relationship but rather on the balance of the burden on one individual against the benefit to another.<sup>118</sup>

The existing U.S. legal regimes reflect a recognition that participants in medical and genetic research deserve something more than simply knowing that they are a part of a socially beneficial study (and maybe a nominal stipend). Rather, as *Grimes* suggests, researchers should have a duty to offer feedback to their subjects when the information they can provide is of significant personal and medical value.<sup>119</sup> Conversely, when certain genetic information is determined to be less valuable to individuals, the duty should not extend so far as to interfere with researchers' other responsibilities.<sup>120</sup> Delineating the boundary between the risks that must be disclosed and those that the researcher may keep to herself is crucial to avoid flooding researchers with responsibilities that might distract them from their research. Therefore, it is essential to thoroughly analyze how different factors, in isolation or in conjunction with others, affect the value of the genetic information in question and impact the decision whether to return it. The next Part discusses this balancing in depth.

#### IV. RECOMMENDATIONS

Taking into consideration the infrastructure in which genetic researchers operate and the relevant ethical and legal foundations, this Article proposes that researchers should have three specific duties when dealing with the return of genetic research results: (1) to plan for the management of incidental findings, (2) to obtain fully informed consent as to the return of results, and (3) to offer to disclose a limited subset of

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chance of survival] to go to the jury on this type of proof. These courts emphasized the fact that defendants' conduct deprived the decedents of a 'significant' chance to survive or recover, rather than requiring proof that with absolute certainty the defendants' conduct caused the physical injury. The underlying reason is that it is not for the wrongdoer, who put the possibility of recovery beyond realization, to say afterward that the result was inevitable." (citations omitted)).

117. *Cf. Pate v. Threlkel*, 661 So. 2d 278, 282 (Fla. 1995) (holding that a doctor's duty to warn relatives of her patient's genetically transferable condition could be discharged by warning the patient herself).

118. *See Richardson & Cho*, *supra* note 108, at 468.

119. *See Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 834 (Md. 2001). For example, in the case of treatable genetic disorders that are indicated by a single gene, the availability of immediate clinical solutions can vastly increase the potential benefits of disclosure to the subject. Pullman & Hodgkinson, *supra* note 5, at 200, 202.

120. This determination should be based on an objective reasonable person standard—that is, by asking what information would be material to a reasonable person in the position of the plaintiff, taking into account the factors described in Part IV.C, *infra*. In the medical context, using an objective standard of materiality to determine what risks must be disclosed for informed consent can provide increased predictability for physicians in medical malpractice proceedings. *See Canterbury v. Spence*, 464 F.2d 772, 787–88 (D.C. Cir. 1972). The objective standard, able to vary based on a defined set of conditions, can be expected to provide similarly predictable measures of liability to genetic researchers.

clinically actionable results. With these duties in place, researchers would have greater responsibility than they do under their present legal obligations, but clearly defining those responsibilities would allow researchers to understand and prepare for them in advance. Likewise, potential research participants would be able to rely on the consistent expectation and enforcement of these three duties.

To best ensure dependability and uniformity, these duties must apply to all genetic studies, regardless of whether the institution is large or small, or whether the materials are taken directly from an individual or from the shelf of a biobank. Much of the literature on the return of results isolates this problem into a single setting (for example, treating primary and secondary research as wholly distinct issues) rather than viewing it from a broader perspective.<sup>121</sup> But in order for potential participants to have a full understanding of their rights and for researchers to know exactly what they are obligated to do, both of which are imperative to prevent chilling the progress of genetic research, all genetic studies should be viewed under one cohesive model. Thus, rather than isolating results by context alone, the context of the study should be only one of several considerations in the determination of a researcher's duty.

#### A. MANAGEMENT OF INCIDENTAL FINDINGS

To get IRB approval, research protocols should be required to include a plan for management of incidental findings. Requiring research designers to consider what kinds of incidental findings they might find and how they would deal with them in advance would better ensure that they keep their subjects' interests in mind throughout the research process. This management duty arises in part from the ethical principles described in the Belmont Report,<sup>122</sup> which requires "an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them."<sup>123</sup> It also stems directly from the Common Rule, which codifies the need for an IRB to ensure suitable protections in every study that involves human subjects.<sup>124</sup> Though the minor details of the specific management plans could be left to the judgment of individual researchers or biobanks, research institutions would, at a minimum, need to consider what types of findings would be most likely to arise and decide how and under what circumstances they would disclose those findings.

Under federal oversight by the HHS, this condition would help achieve national uniformity in the field of genetic research by requiring a

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121. See, e.g., Laura M. Beskow & Wylie Burke, *Offering Individual Genetic Research Results: Context Matters*, 38 SCI. TRANSLATIONAL MED. 20 (2010).

122. See *supra* Part II.A.

123. THE BELMONT REPORT, *supra* note 56, at C.1.

124. See *supra* Part III.A.

consistent level of consideration of the issue of returning results, without imposing overly restrictive constraints that could limit the field's development. This, in turn, would help standardize what types of results would be returned and thereby allow greater reliance by individuals who would better understand what to expect from participating in genetic research studies. In addition, asking study designers to think about the implications of incidental findings ahead of time would not only ensure appropriate administrative procedures, but would also make researchers more alert to the possibility that they might discover information that could be relevant to a subject's health. This increase in understanding and awareness would alleviate some of the misalignment of interests about which the *Grimes* court was concerned.<sup>125</sup> If researchers' protocols explicitly required them to recognize their subjects' interests, they would not only consider the societal impact of the study, but would also be required to keep in mind the individual participants' interests throughout the research process.

Notably, the duty described in this Subpart should be limited only to requiring a management plan. Neither federal nor state governments should require researchers to actively seek out incidental findings, as that could seriously impede the progress of research by distracting investigators from their primary purpose. Likewise, biobanks should—within the existing guidelines and those proposed herein—make their own decisions about the precise guidelines that they will uphold with respect to return of results, as several already have,<sup>126</sup> because they are most familiar with their own operations. With the advent of a legal duty to enforce those standards, biobanks could continue to develop their policies and even look to other biobanks to see what procedures are most effective, in order to work toward industry-wide best practices. For instance, if biobanks were required to report their plans at a federal level, researchers across the country could consider and integrate others' policies into their own governance. This shared knowledge would benefit all genetic studies, whether they use biobanked or individually collected materials, and allow participants to rely on researchers to have a well-tested strategy to deal with incidental findings.

#### B. FULLY INFORMED CONSENT

As a part of their duties to provide informed consent, researchers should be required to fully describe and discuss the risks and benefits of knowing certain types of genetic information, in addition to the physical risks of the study. Participants should then be able to opt out of receiving results. Once planned for in their research protocols, this requirement

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125. See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 837–38 (Md. 2001).

126. See ALSPAC ETHICS & LAW COMM., *supra* note 55.

would not impose any significant burden on researchers. Nor is the requirement of fully informed consent controversial; it arises out of regulatory,<sup>127</sup> common law,<sup>128</sup> and ethical principles alike.<sup>129</sup>

In a biobank setting, the researcher should also be made aware of the informed consent requirements so that she understands her responsibilities with regard to the participants' rights.<sup>130</sup> Because it is often difficult to track down individuals at the start of each study, contributors to biobanks could agree in advance to have their materials used in specific types of studies, which they could indicate on an intake form—for instance, by marking assent to cancer studies but not to mental health studies. When a study diverges significantly from the types described in the initial intake form, re-contact would be necessary to procure additional consent. Viewing the informed consent process as one in which the subjects entrust their privacy rights in their DNA to the researchers, this process would cement the researchers' obligation to protect those rights while streamlining the research process as much as possible.<sup>131</sup>

The heightened informed consent requirement arises from legal and ethical foundations and would provide several benefits to research participants. Based on both the regulations in the Common Rule and the special relationship between researchers and subjects,<sup>132</sup> it would help alleviate the problem of therapeutic misconception. By clarifying the precise nature of the research, full informed consent would ensure that participants understand exactly what they are agreeing to when deciding whether to be informed of certain types of results. Furthermore, a full explanation of what one could expect by donating genetic material to a study that would provide no subsequent feedback would provide crucial respect for individual autonomy. The requirement of an opt-out provision would ensure that participants who decide they do not want to know certain kinds of results are able to exercise that choice.

The duty of fully informed consent should aim to set a standard for communication between researchers and participants, even if that means that some individuals are dissuaded from participating in genetic research by what they learn during the informed consent process. Over time, standardized researcher-subject communication would help develop a sense of trust in the system that would ultimately strengthen public support for genetic research.<sup>133</sup> Because all parties involved stand

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127. See, e.g., Protection of Human Subjects, 45 C.F.R. § 46.116 (2009).

128. See, e.g., *Grimes*, 782 A.2d at 850–51.

129. See, e.g., THE BELMONT REPORT, *supra* note 56, at C.1.

130. See Richardson & Cho, *supra* note 108, at 471.

131. *Id.* at 469.

132. See *supra* notes 127–128.

133. See, e.g., Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 344 (2007) (“[B]y failing to respect donors, the biobanks put at risk the long-term interests of biomedical science, which can only prosper

to benefit from the enforcement of fully informed consent as to the return of genetic research results, it should be a priority in framing a set of responsibilities.

### C. DISCLOSURE OF LIMITED CLINICALLY ACTIONABLE RESULTS

Finally, researchers should have a legal duty to offer to disclose certain results that present a serious and foreseeable harm and to have a plan for referral to genetic counseling. Like having a management plan, this would ensure both procedural protections for and thoughtful consideration of the possibility of actionable results before a study begins. By requiring only that researchers offer to disclose their findings, this duty would respect the participants' rights to know their personal information and, alternatively, to exercise personal autonomy should they not want to know. Stemming in large part from the special relationship between genetic researchers and their human subjects, this duty to warn would require that a researcher disclose genetic information if that information could help a participant avoid a serious and foreseeable harm.<sup>134</sup> To narrow the reach of the duty, it is critical to determine what types of genetic results would constitute such harm.

A starting point is that results should only be returned when they are "clinically actionable"—that is, when they have the "potential to change immediate medical care."<sup>135</sup> It is not sufficient, however, that a finding be medically related, because the burden on the researcher to disclose all potential medical risks would be overwhelming. Several variables interplay in the judgment of which clinically actionable results must be disclosed, most importantly the severity of the disease (that is, the finding's potential impact on health or reproductive decisionmaking), the probability of actually developing the disease, and the availability and effectiveness of treatment. The greater the degree to which these factors are present, the more likely it should be that the researcher has a duty to inform the subject of the genetic finding.

Depending on the extent of the severity, probability, and treatability, weighing these factors can split results into multiple categories of clinical actionability: results that must be returned, results that may be returned at the researcher's discretion, and results that may never be returned.<sup>136</sup> For example, the discovery of a genetic predisposition to a severe or life-threatening disease that is highly likely to materialize and for which

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with the trust and support of the population.").

134. See *supra* notes 113–115 and accompanying text.

135. Fullerton et al., *supra* note 3, at 425.

136. See Wolf et al., *supra* note 25, at 235 tbl.5. Wolf describes the three categories as those in which disclosing results has a "Strong Net Benefit," a "Possible Net Benefit," or an "Unlikely Net Benefit." *Id.*

treatment is available would always need to be reported.<sup>137</sup> On the other hand, a result that does not by itself carry any health implications, such as misattributed paternity, would not require disclosure.<sup>138</sup>

The degree of clinical actionability alone, however, does not clarify what researchers should be required to disclose when a finding falls in the middle of this spectrum. In making determinations about which of these results to share, researchers must consider additional factors, especially when those factors have powerful ethical implications.<sup>139</sup> These factors should include the extent to which the subject relies on the researcher for getting care and whether the subject is particularly vulnerable.<sup>140</sup> The possible negative consequences that the participant faces as a result of her participation in the research—for instance, the potential that her genetic information could be used for discriminatory purposes if her DNA makeup were to be exposed—should also be considered.<sup>141</sup> When de-identified information is easily re-linked to subjects, it should be imperative, as a matter of fairness and reciprocity, to return information to them because of their increased vulnerability.<sup>142</sup>

Furthermore, the ease of return should play a crucial role. If there is a minimal burden on the researcher to return the information, as is generally the case the closer the finding is in time and subject matter to the initial study, she has a much less compelling reason not to return the results.<sup>143</sup> For instance, if a finding were closely related to the study's aims, not only would the burden likely be minimal, but the participant's reliance on the researcher would also likely be strong.<sup>144</sup> Similarly, in certain types of studies, such as pedigree studies, researchers may have long-term relationships with their subjects that facilitate trust and communication.<sup>145</sup> In contrast, researchers who use biobanked materials

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137. *See id.*

138. *See id.*; *see also* Cho, *supra* note 28, at 282 (“[T]he potential benefits of genetic research may be informational only, rather than directly providing therapeutic value. Nevertheless, consideration of circumstances in which the information might change clinical decisions, such as the availability of an effective intervention or prevention, is important.”).

139. *Cf.* Greely, *supra* note 133, at 360 (“Regardless of the moral and legal obligations, it would be extremely unwise for researchers not to disclose such risks. Consider what happens after the first lawsuit by the bereaved family of a research subject whose life would have been saved had researchers revealed a risk they discovered. Whether or not the plaintiffs win, those researchers and their institution will be branded as heartless, interested in subjects only as laboratory animals, and all biomedical research will feel the fallout.”).

140. *See* Richardson & Cho, *supra* note 108, at 469 tbl.1. Vulnerability is measured by asking: “How much difference would getting the information in question make to the health or welfare of the participant?” *Id.*

141. *Id.*

142. *Id.*

143. *See* Cho, *supra* note 28, at 282–83.

144. *See, e.g.,* Ewen Callaway, *Gene Hunt Is on for Mental Disability*, 484 NATURE 302, 303 (2012).

145. Cho, *supra* note 28, at 282–83.

may have no contact with the human subjects themselves, and thus the burden of returning results may be significantly greater.<sup>146</sup>

The balance of these factors should depend on the particulars of the study and the finding in question. For example, one research project's ethical review board struggled to determine whether an incidental finding of an increased risk of colon cancer must be disclosed when discovered during a study on mental disabilities in children.<sup>147</sup> Although the board decided to disclose the information in one instance on the theory that the child patients relied on the researchers for medical information, researchers in similar studies choose not to disclose such findings.<sup>148</sup> Such a determination could rightly vary between studies due to the structure of the study and the relationship and reliance between the researcher and the subject.

Other determinations should be more dependent on the nature of the disease. For example, one review board determined that a mutation of a gene that predisposes individuals to deep vein thrombosis and pulmonary embolisms should be disclosed only when an individual is homozygous for the mutation because the increase in risk for the disease only at that point rises to the level at which preventative measures outweigh the risks of "creating 'worried well' individuals among those still unlikely to develop symptoms."<sup>149</sup> Despite their complicated and delicate nature, however, the interrelationship of these factors provides a framework for making these decisions.

Due to their complexity, determinations about precisely which results should be returned to research participants should be made by boards consisting of geneticists, policymakers, and others who are familiar with the impact of different genes and diseases. These evaluations should evolve over time as treatments become more readily available, tests improve in their accuracy, and electronic medical records make it easier to share information about both clinical health and genetics.<sup>150</sup> One promising solution to these challenges would be to establish ongoing IRB subcommittees that would implement guidelines for what types of findings researchers should return and act as screening boards to review any results that arise.<sup>151</sup> These subcommittees could also provide a mechanism for national review by reporting their decisions to a centralized board, which over time would help develop a uniform

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146. *See id.* at 282.

147. *Id.* at 282-83.

148. *Id.*

149. Fullerton et al., *supra* note 3, at 426.

150. *Id.* at 428. Increasing access to electronic medical records may help determine whether it is necessary to provide results: If a person already shows clinical signs of an otherwise actionable result, for instance, it may be unnecessary to counsel her about her genetic predisposition. *Id.*

151. *See id.* at 425.

national consensus as to which results should be returned. Removing the responsibility for these kinds of judgment calls from the researcher would both conserve research resources and ensure appropriate review by a board that is familiar with the ever-changing clinical and ethical implications of returning results.

Once the IRB subcommittee has determined that results must be communicated, researchers would have a duty to refer the participant to a genetic counselor when the information has implications that the researcher is unable to communicate to the subject herself. Although researchers generally hold the most information about the subject's genetics, they do not have the clinical training or experience of physicians and therefore may be ineffective when communicating serious and oftentimes confusing genetic information to a layperson.<sup>152</sup> But simply suggesting that "donors seek additional help and guidance from physicians or genetic counselors on the assumption they will do so is shortsighted and does not take into account the realities of the situation: there is evidence that many physicians still do not possess sufficient understanding of the implications of genetic tests."<sup>153</sup> Therefore, researchers should be responsible for actively connecting their subjects to genetic counselors who can thoroughly explain the implications of any findings.

The requirement of referral for genetic counseling should also apply in the context of biobanking. Some biobanks choose not to engage in individual feedback at all because of the fear that information disclosed outside of the clinical setting provides neither a full view of the individual's medical record nor appropriate counseling.<sup>154</sup> These policies, however, prevent subjects from learning of even the most important information. To preserve their right to their personal information, the duty to refer to a genetic counselor would guarantee that feedback would be given in an appropriate manner but would not overburden a researcher who is untrained in and unprepared for providing genetic information in a clinical setting.

#### CONCLUSION

By analyzing and balancing the varying perspectives on returning genetic research results while keeping in mind relevant practical, ethical, and legal considerations, this Article has aimed to develop limited, mutually beneficial duties that better align the interests and incentives of the involved parties. With so much at stake on all sides of the issue, this is a crucial point in the development of the laws and policies that impact the field of genetic research. Establishing the limited duties described in

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152. See Fisher, *supra* note 74, at 459.

153. *Id.*

154. Zawati & Rioux, *supra* note 28, at 616; see U.K. BIOBANK, *supra* note 33, at 7.

this Article would clarify subjects' and researchers' respective rights and responsibilities and ensure their ongoing enforcement. These duties would help shape society's understanding of the interplay between science, ethics, and law in a manner that not only promotes ongoing scientific development, but also protects the people who volunteer their bodies to make such research possible.