Note

Incorporating Cost into the Return of Incidental Findings Calculus: Defining a Responsible Default for Genetics and Genomics Researchers

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Sandy Cohen lost both her mother and grandmother to breast cancer.[1] Fearing that she would also become a victim of breast cancer, Sandy underwent genetic testing.[2] The testing revealed that Sandy had a BRCA1 mutation.[3] Approximately fifty-five to sixty-five percent of women who inherit a BRCA1 mutation will develop breast cancer sometime during their lives.[4] Genetics and genomics research led to the discovery of the BRCA1 gene mutation.[5] Because of this discovery, women like Sandy Cohen[6] are now empowered to take life-saving precautions to prevent the development of breast cancer.

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1. Basser Research Ctr. for BRCA, *Patient Stories*, PENN MEDICINE ABRAMSON CANCER CTR., https://cancer.pennmedicine.org/about/patient-stories/brca-sandy (last visited Nov. 30, 2015).

2. *Id.*

3. *Id.*

4. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing Fact Sheet*, NAT'L CANCER INST., http://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet (last visited Nov. 30, 2015).

5. *See* David Botstein & Neil Risch, *Discovering Genotypes Underlying Human Phenotypes: Past Successes for Mendelian Disease, Future Approaches for Complex Disease*, 33 NATURE GENETICS 228, 229 (2003).

6. *See* Angelina Jolie, Opinion, *My Medical Choice*, N.Y. TIMES (May 14, 2013), http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html.

Now, imagine that Sandy Cohen did not receive genetic testing, but rather enrolled as a participant in a genomics research study. The researchers are studying colon cancer. When the researchers sequence Sandy's genome, they stumble upon the BRCA1 gene mutation. They were not looking for the BRCA1 gene mutation and this mutation is not related to the study. Do the researchers have an ethical or legal duty to offer these results to Sandy? This example illustrates the "vigorous debate"[7] over researchers' duty to return individual research results and incidental findings to research participants. An incidental finding, also known as a secondary finding, is "a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study."[8] The debate over returning incidental findings has been a hot topic in medical and legal circles for many years[9] and is described as "one of the thorniest current challenges."[10] Currently, no federal or state laws regulate the disclosure of these findings.[11] Although many agree that ethical duties arise in returning certain individual results and incidental findings,[12] the legal implications are much more opaque.[13] This legal ambigui-

7. Laura M. Beskow & Wylie Burke, *Offering Individual Genetic Research Results: Context Matters*, 2 SCI. TRANSLATIONAL MED. 1, 1 (2010).

8. Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 219 (2008) [hereinafter Wolf et al., *Managing Incidental Findings*]. An incidental finding is not the same as an individual research result. Simply stated, if the researcher was looking for the finding, then the finding is an individual research result; if not, then the finding is an incidental finding. Erik Parens et al., *Incidental Findings in the Era of Whole Genome Sequencing?*, 43 HASTINGS CTR. REP. 16, 18 (2013).

9. *See* Marianna J. Bledsoe et al., *Return of Research Results from Genomic Biobanks: Cost Matters*, 15 GENETICS MED. 103, 103 (2013).

10. Gina Kolata, *Genes Now Tell Doctors Secrets They Can't Utter*, N.Y. TIMES (Aug. 25, 2012), http://www.nytimes.com/2012/08/26/health/research/with-rise-of-gene-sequencing-ethical-puzzles.html (quoting Francis Collins, Director of the National Institutes of Health).

11. *See* Amy L. McGuire et al., *Can I Be Sued for That? Liability Risk and the Disclosure of Clinically Significant Genetic Research Findings*, 24 GENOME RES. 719, 719 (2014) ("Yet, no United States regulations directly address this issue, and there is no clear case law to rely on."); Susan M. Wolf, *The Role of Law in the Debate over Return of Research Results and Incidental Findings: The Challenge of Developing Law for Translational Science*, 13 MINN. J.L. SCI. & TECH. 435, 436 (2012) [hereinafter Wolf, *Role of Law*] ("There is no law directly on point.").

12. *See* Elizabeth R. Pike et al., *Finding Fault? Exploring Legal Duties To Return Incidental Findings in Genomic Research*, 102 GEO. L.J. 795, 809 (2014).

13. *See* Wolf, *Role of Law*, *supra* note 11, at 437.

ty raises concerns as ethical recommendations for researchers evolve and seem to establish a standard of care for the research enterprise.[14] An established standard of care may lead to legal liability for researchers.[15]

Researchers may bear the additional costs that the threats of liability and legal ambiguity impose.[16] Numerous questions arise.[17] What results should be disclosed to participants? Who should disclose the results? Who should pay for the results? How long does a potential duty last? What are the potential costs if researchers do not return incidental findings? The cost and resource implications of a duty to return incidental findings may severely inhibit the advancement of genetics and genomics research and threaten the societal benefit of continued research.[18] Furthermore, as researchers continue to identify new genetic and genomic variants, researchers will discover more incidental findings and the costs of returning these results will likely increase.[19] Therefore, an informed analysis of the medical, legal, and economic implications is needed now to ensure appropriate standards are created.

Compounding this issue are funding concerns that jeopardize future research efforts and life-saving discoveries.[20] These

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14. *See* Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomics Research*, 14 GENETICS MED. 473, 473 (2012).

15. *Id.*

16. *See* Susanne B. Haga & Jennifer Q. Zhao, *Stakeholder Views on Returning Research Results*, *in* 84 ADVANCES IN GENETICS 42, 68–69 (Theodore Friedmann et al. eds., 2013).

17. *See, e.g.*, KAREN H. ROTHENBERG & LYNN WEIN BUSH, THE DRAMA OF DNA: NARRATIVE GENOMICS 3 (2014) ("Controversial issues abound—such as determining whether, what, to whom, when and how genomic information should be disclosed to individuals . . . ."); Clayton & McGuire, *supra* note 14.

18. *See* Gail P. Jarvik et al., *Return of Genomic Results to Research Participants: The Floor, the Ceiling, and the Choices in Between*, 94 AM. J. HUM. GENETICS 818, 820 (2014); Michael R. Ulrich, *Resource Restraints: Rethinking Disclosure of Individual Genomic Findings*, 17 MICH. ST. U. J. MED. & L. 127, 145 (2012) ("With all of the good that has come from conducting research and all the potential discoveries that lie in wait in genomic research it is vital that a suitable obligation to return individual results be clarified.").

19. *See* Bledsoe et al., *supra* note 9, at 104.

20. Sam Stein, *House GOP Votes Down NIH Funding Measure One Day After Members Praised NIH Funding*, HUFFINGTON POST (Mar. 19, 2015), http://www.huffingtonpost.com/2015/03/19/nih-funding-_n_6901932.html; Liz Szabo, *NIH Director: Budget Cuts Put U.S. Science at Risk*, USA TODAY (Apr. 23, 2014), http://www.usatoday.com/story/news/nation/2014/04/23/nih-budget-cuts/8056113; *Francis Collins Warns of 'Devastating' Effect of Budget Crisis on NIH-Funded Research*, GENOMEWEB (Oct. 7, 2015), https://www.genomeweb.com/research-funding/francis-collins-warns-devastating-effect-budget-crisis-nih-funded-research.

funding shortages have the immediate effect of denying innovative research projects. The National Institutes of Health (NIH) was once able to fund one in three research proposals, but in the past ten years, this funding ratio has dropped to one in six.[21] NIH's budget has lost twenty-five percent of its purchasing power over the last decade due to inflation.[22] Limited funding also presents long-term problems of current researchers leaving the field and fewer researchers coming into the field.[23] Studies have shown that scientists are considering moving from the United States to other countries to do research.[24] Many commentators are concerned that continued shortages in research funding will have lasting negative repercussions for genetic and genomic research.[25]

Several articles have focused on the ethical and legal issues surrounding the problem of incidental findings in genetics and genomics research.[26] This Note analyzes the cost implications of a duty to return incidental findings and how these cost implications should shape future policy recommendations for genetics and genomics research. This Note takes previous recommendations one step further to provide an ethically, legally,

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21. Szabo, *supra* note 20; *see also* MacKenzie Elmer, *Federal Budget Woes Slow Medical Research*, DES MOINES REG. (Sept. 29, 2014), http://www.desmoinesregister.com/story/news/education/2014/09/29/federal-budget-woes-slow-medical-research/16411759.

22. Szabo, *supra* note 20; *see also* Editorial, *Elizabeth Warren Plan Would Bolster NIH Funding*, BOS. GLOBE (Mar. 6, 2015), http://www.bostonglobe.com/opinion/editorials/2015/03/05/elizabeth-warren-plan-would-bolster-nih-funding/rlFDSwUz5zhNjXklIPCPWN/story.html.

23. Szabo, *supra* note 20; *see also* John LaMattina, *The NIH Needs More Funding—Here's a Proposal That Can Help*, FORBES (Mar. 5, 2015), http://www.forbes.com/sites/johnlamattina/2015/03/05/the-nih-needs-more-funding-heres-a-proposal-that-can-help; Claire Pomeroy & Eric. R. Kandel, Opinion, *Cutting Budgets for Medical Research Is Dangerous*, CNN (June 6, 2014), http://www.cnn.com/2014/06/06/opinion/pomeroy-kandel-medical-research.

24. Szabo, *supra* note 20.

25. *See, e.g.*, *id.*; Pomeroy & Kandel, *supra* note 23.

26. *See* L. Black et al., *Funding Considerations for the Disclosure of Genetic Incidental Findings in Biobank Research*, 84 CLINICAL GENETICS 397, 397 (2013) ("Much of the detail about how [incidental findings] should be handled comes from scientific and ethics literature."). *See generally* Stephanie A. Alessi, *The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?*, 64 HASTINGS L.J. 1697 (2013) (addressing the ethical foundations for a duty to return incidental findings and the potential sources of legal duties); Richard L. Furman, Jr., *Genetic Test Results and the Duty To Disclose: Can Medical Researchers Control Liability?*, 23 SEATTLE U. L. REV. 391 (1999) (analyzing potential legal liability to researchers under claims in tort, contract, and property law); Pike et al., *supra* note 12 (proposing that researchers' potential legal liability should be addressed through the informed consent process).

and fiscally responsible default rule to apply when researchers are not sure whether offering to return results is appropriate. This Note proposes that researchers should default to offering to return incidental findings in genomics or genetics research to participants, unless the researchers weigh the costs and benefits of returning versus the costs and benefits of not returning and reasonably conclude that they should not return the incidental findings. The default rule places a minimal burden on researchers and also provides guidance and a sense of security from the threat of future legal liability. Part I of this Note discusses the history of medical research liability and the debate over the issue of returning research results and incidental findings. Part II analyzes the cost implications of current recommendations for researchers faced with incidental findings in genetics and genomics research. Part III argues that policymakers need to take cost implications into account, proposes some potential recommendations that would address these cost considerations, and defines a default rule that will provide guidance without overly burdening the genetics and genomics research enterprise.

I. MEDICAL RESEARCHER LIABILITY AND THE DEBATE OVER RETURN OF RESEARCH RESULTS AND INCIDENTAL FINDINGS

Medical research has a long history in the United States.[27] Beginning in the 1960s, research institutions started to develop guidelines to ensure the protection of human subjects in research.[28] Section A will briefly discuss the history of medical research and researcher liability. Section B will present the debate in genetics and genomics research over whether researchers should offer results to participants. Finally, Section C will introduce some of the cost implications of returning research results to participants.

A. HISTORY OF MEDICAL RESEARCH AND RESEARCHER LIABILITY

The goal of medical research is to "pursue generalizable

27. For a general overview of the medical and research history in the United States, visit *History of Medicine*, NAT'L INSTITS. HEALTH, http://www.nlm.nih.gov/hmd (last updated Oct. 21, 2015).

28. Amy L. Davis & Elisa A. Hurley, *Setting the Stage: The Past and Present of Human Subjects Research Regulations*, *in* BASIC BIOETHICS: HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE 9, 9–11 (I. Glenn Cohen & Holly Fernandez Lynch eds., 2014).

knowledge that will benefit society."[29] On its face, medical research does not explicitly create a duty between the researcher and the participant.[30] Unlike physician-patient relationships, researcher-participant relationships are not considered fiduciary relationships, which is a relationship held in trust.[31] Thus, researchers are not required to act "primarily for the benefit of the individual research subject."[32]

The rights and wellbeing of research participants, however, are not inconsequential. The "Common Rule"[33] and FDA regulations govern human subjects research.[34] The "Common Rule," also known as the Federal Policy for the Protection of Human Subjects, applies to nearly all federally-funded human subjects research.[35] As a part of obtaining "legally effective informed consent of the subject,"[36] the Common Rule requires that researchers disclose reasonably foreseeable risks and benefits to

29. Ulrich, *supra* note 18, at 128.

30. This lack of a duty is in stark contrast to physicians who are "regarded as fiduciaries of their patients and as such are expected to act in their patients' best interests." Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 242 (2003) (footnotes omitted).

31. *See* Franklin G. Miller et al., *Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants?*, 36 J.L. MED. & ETHICS 271, 273 (2008) ("Unlike the physician, the investigator has not undertaken to act in the subject's best interests when entering into the relationship; she has not taken on a fiduciary role.").

32. McGuire et al., *supra* note 11, at 721; *see also* Wolf, *Role of Law*, *supra* note 11, at 443 ("Both law and ethics have conceived of the research and clinical spheres as generally quite distinct.").

33. 45 C.F.R. § 46 (2014). In September 2015, the Department of Health and Human Services announced proposed revisions to the Common Rule. *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 80 Fed. Reg. 53,931, 53,936 (proposed Sept. 8, 2015), https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects. The proposed rule revision seeks to make the informed consent process more meaningful. *Id.*

34. 21 C.F.R. §§ 50, 56 (2015). These regulations apply to research involving experimental drugs, biological products, and medical devices subject to FDA approval. *Id.* Similar to the Common Rule, the FDA regulations require informed consent and IRB review and approval. *Id.* §§ 50.20–50.27; *id.* §§ 56.103, 56.109, 56.111. Unlike the Common Rule, the FDA regulations provide fewer exceptions to the informed consent requirements and fewer waivers. *Compare* 45 C.F.R. § 46.116(c)–(d) (2014) (delineating the Common Rule's requirements for modifying or waiving consent), *with* 21 C.F.R. § 50.23 (2015) (listing FDA regulations' exceptions from general consent requirements).

35. *See Federal Policy for the Protection of Human Subjects ("Common Rule")*, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html (last visited Nov. 30, 2015).

36. 45 C.F.R. § 46.116.

participants.[37] The Common Rule also directs researchers to minimize potential risks to participants and ensure that the risks are reasonable in relation to the anticipated benefits.[38] The Common Rule, however, does not create an express cause of action for participants who allege a violation.[39]

Although the Common Rule does not enable participants to sue researchers, research participants may be able to recover against researchers under a negligence regime.[40] While lawsuits against researchers have been historically rare, research-related litigation has been increasing.[41] Several cases illustrate the recent shift in courts' treatment of researcher-participant relationships and how these relationships may give rise to duties never before anticipated.

In *Grimes v. Kennedy Krieger Institute*,[42] the Maryland Court of Appeals held that "the very nature of nontherapeutic research on human subjects can, and normally will, create special relationships out of which duties arise."[43] *Grimes* involved research on lead-paint abatement in houses rented to families with young children.[44] The researchers found that the plaintiffs' children had elevated levels of lead in their blood.[45] Plaintiffs brought suit arguing that the researchers failed to warn them of the hazardous levels of lead paint.[46] Vacating the lower court's decision,[47] the court of appeals found that the researchers had a duty given the researchers' ability to "anticipate, discover, and understand the potential risks to the health of their subjects."[48]

A few years before *Grimes*, the United States District Court for the Northern District of Illinois found in *Blaz v. Michael Reese Hospital* that a physician leading a research program had a duty to warn a patient, whom the physician had

37. *Id.*

38. *Id.* § 46.111.

39. *See* Susan M. Wolf et al., *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361, 368 (2008) [hereinafter Wolf et al., *Law of Incidental Findings*].

40. *See* Jansson, *supra* note 30, at 236.

41. *See* Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40, 40 (2003).

42. 782 A.2d 807 (Md. 2001).

43. *Id.* at 834–35.

44. *Id.* at 819.

45. *Id.* at 825.

46. *Id.* at 825–26.

47. *Id.* at 858.

48. *Id.* at 851.

never treated, of the risks of previous treatment received.[49] In *Blaz*, the plaintiff participated in a research study performed by the defendant, a physician who had never treated the plaintiff.[50] The study analyzed the connection between x-ray treatments, which the plaintiff had undergone as a child, and the prevalence of tumors.[51] Almost 20 years after the study, the plaintiff developed neural tumors and sued the physician for failure to warn him of the study's finding that he might be at an increased risk for developing tumors.[52] Even though the defendant did not have a physician-patient relationship with the plaintiff, the district court found that the defendant owed a duty to the plaintiff because of the reasonable foreseeability of harm, the negligible burden on the defendant to warn, the defendant's "special position to acquire the information"[53] and the plaintiff "was in no position to find out"[54] the information. Like *Grimes*, the court in *Blaz* also found that the defendant's position as the head of the research program created a "special relationship" required "for a finding of duty in the absence of a physician-patient relationship."[55]

Some commentators argue that cases like *Grimes* and *Blaz* represent a larger trend of increased liability exposure for medical researchers and that these cases could lead to more lawsuits in the future.[56] While the legal duty of researchers remains unclear and scarcely addressed in courts, the issue of returning research results and incidental findings presents some interesting challenges that the court will likely have to face someday in the near future.

B. DEBATE OVER RETURN OF RESEARCH RESULTS AND INCIDENTAL FINDINGS

The use of genetics and genomics for nontherapeutic research[57] raises challenging ethical and legal issues for re-

49. 74 F. Supp. 2d 803, 805 (N.D. Ill. 1999).
50. *Id.* at 804.
51. *Id.*
52. *Id.*
53. *Id.* at 805–06.
54. *Id.*
55. *Id.* at 806–07.
56. *See, e.g.*, Jansson, *supra* note 30, at 230 ("This period of increased legal and public scrutiny of the research enterprise will likely lead to a dramatic rise in lawsuits by human subjects.").
57. It is important to note a distinction between therapeutic research, which has a possibility for immediate benefit to the research participants, and nontherapeutic research, which does not offer immediate clinical benefits to

searchers. During the course of genetics and genomics research, researchers are likely to discover incidental findings. While incidental findings can arise in any area of medical research,[58] genetics and genomics research raises particular concerns because of the likelihood and scope of potential incidental findings.[59] Some of these findings have clear clinical significance,[60] whereas other incidental findings have no clear significance.[61]

Currently, researchers and others in the field are reaching a general consensus that certain ethical obligations[62] require the return of incidental findings in some circumstances.[63] It is important to note that the ethical duty to return incidental findings is distinct from the issue of legal obligations to return incidental findings.[64] Potential legal liability and the sources for liability for failure to return incidental findings remains a point of contention.[65] Neither the Common Rule nor the FDA regulations directly address incidental findings.[66] Although no court

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the participants. *See* Matthew P. Gordon, *A Legal Duty To Disclose Individual Research Findings to Research Subjects?*, 64 FOOD & DRUG L.J. 225, 227 (2009).

58. *See, e.g.*, *id.* at 224–26 (discussing incidental findings in MRI research and CT colonography).

59. Pike et al., *supra* note 12, at 800.

60. *See, e.g.*, Naomi H. Brodersen et al., *Anticipated Reactions to Genetic Testing for Hereditary Non-Polyposis Colorectal Cancer Susceptibility*, 66 CLINICAL GENETICS 437, 437 (2004) (explaining that hereditary non-polyposis colorectal cancer disorder "has been shown to be caused by mutations of DNA mismatch repair genes").

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

62. *See* Ulrich, *supra* note 18, at 136–43 (grounding an ethical obligation to return incidental findings in respect for the participants, beneficence, reciprocity, and other ethical principles). *But see* Leslie A. Meltzer, *Undesirable Implications of Disclosing Individual Genetic Results to Research Participants*, 6 AM. J. BIOETHICS 28, 28 (2006) ("[T]heir justification for disclosure rests on the mistaken view that principles of beneficence, respect, reciprocity, and/or justice ethically require researchers to offer participants individual genetic results.").

63. *See* Clayton & McGuire, *supra* note 14 ("There is substantial consensus that people should be offered results that could trigger interventions that are lifesaving or that could avert serious adverse health outcomes . . . .").

64. Wolf, *Role of Law*, *supra* note 11, at 440–41.

65. *See* Pike et al., *supra* note 12, at 830; Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 362 (discussing the uncertainty of whether and when a researcher may be liable for failing to return incidental findings).

66. For a discussion of how several provisions of the federal regulations governing human subjects research are relevant to the disclosing and managing of incidental findings, see Wolf et al., *Law of Incidental Findings*, *supra*

has directly addressed the issue of a researcher's legal duty to disclose incidental findings, increased researcher liability claims and recent court cases create fear of legal liability for genetics and genomics researchers.

While *Grimes* and *Blaz* suggest that researchers have some sort of a special duty to their participants, only one case arguably addresses the issue of whether a researcher has a duty to disclose individual research findings. In *Ande v. Rock*, the plaintiffs sued researchers for failing to inform them that their child had cystic fibrosis.[67] The plaintiffs had their first child in 1993 and at that time, the plaintiffs received a pamphlet describing the cystic fibrosis research.[68] The plaintiffs' child was placed in the "blinded control" group, which meant that although the plaintiffs' child tested positive for factors indicative of cystic fibrosis, the researchers did not inform the plaintiffs.[69] Two years later, the child was diagnosed with cystic fibrosis and the plaintiffs had already conceived a second child, who was also diagnosed with cystic fibrosis.[70] The court ultimately dismissed the plaintiffs' medical malpractice and negligence claims.[71] For the medical malpractice claim, the court found that no physician-patient relationship existed between the plaintiffs and any of the defendants, so the medical malpractice claim could not prevail.[72] On the claim of negligence, the lower court found that the claim was time-barred and plaintiffs did not appeal the ruling.[73]

Although the court never reached the issue of the researchers' duty to return individual research results to the plaintiffs, some legal scholars argue that *Ande* is still informative.[74] *Ande* may reflect courts' resistance to requiring researchers to disclose individual research results.[75] The lack of litigation regarding return of research results and incidental findings, however, has failed to calm fears of legal liability in the research community.[76]

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note 39, at 366–68.

67. 647 N.W.2d 265, 268 (Wis. Ct. App. 2002).

68. *Id.* at 269.

69. *Id.*

70. *Id.* at 270.

71. *Id.* at 276; *id.* at 268 ("The circuit court dismissed all of the state claims, except those for medical malpractice.").

72. *Id.* at 272.

73. *Id.* at 269.

74. *See, e.g.*, Gordon, *supra* note 57, at 234.

75. *See id.*

76. *See* Wolf, *Role of Law*, *supra* note 11, at 437 ("It appears to be little

In addition to the previous litigation involving researchers and courts expanding the duties of researchers, ethical obligations may create unintended consequences that burden the research enterprise and put researchers in the firing line for negligence lawsuits.[77] Several articles have addressed the fear that ethic recommendations will be misconstrued as legal obligations.[78] As researchers adopt these ethical recommendations, these new practices may give rise to a corresponding legal standard of care for researchers.[79] Two scholars, Ellen Wright Clayton and Amy McGuire, stated "One thing is certain—if these practices become routine, they *will* be legally required. This is the way tort law has worked for decades."[80]

Besides the concerns of ethical obligations morphing into legal obligations, the current ethical recommendations provide inconclusive guidance for researchers, leading to inconsistent practice.[81] Although many commentators and researchers agree that "[incidental findings] should be returned only when they are analytically valid, have significant health implications, and are clinically actionable,"[82] these criteria fail to provide all the answers.[83] Inconsistent practice arguably can lead to legal lia-

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reassurance that no court . . . has yet found anyone liable for mishandling return of results or incidental findings in the context of human subjects research.").

77. *See, e.g.*, W. Nicholson Price II, *Legal Implications of an Ethical Duty To Search for Genetic Incidental Findings*, 13 AM. J. BIOETHICS 48, 48 (2013) (explaining that ethical obligations may create a standard of care and "provide grounds for a negligence lawsuit").

78. *See, e.g.*, Wolf, *Role of Law*, *supra* note 11, at 438 ("Though law and ethics are sometimes confused, they are distinct.").

79. *See* Clayton & McGuire, *supra* note 14, at 475 (discussing how ethical obligations may become evidence of standard of care for researchers); Pike et al., *supra* note 12, at 815 ("[A]s this emerging ethical obligation increasingly becomes standard or customary practice in research, the emerging ethical obligation could give rise to a legal obligation to return [incidental findings], the failure of which could result in legal liability."); Price, *supra* note 77, ("[I]f an ethical duty to search for incidental genetic findings arises and becomes widespread at some point in the future, it may become the legal standard of care . . . .").

80. Clayton & McGuire, *supra* note 14, at 475.

81. *See* Pike et al., *supra* note 12, at 808–09.

82. *Id.* at 809.

83. *See* Gordon, *supra* note 57, at 253 ("[T]he determination whether a particular individual research finding has clinical utility may often be far from simple . . . . In addition, the investigators may not be adequately trained to assess clinical utility."); Robert Klitzman, *Questions, Complexities, and Limitations in Disclosing Individual Genetic Results*, 6 AM. J. BIOETHICS 34, 35 (2006) ("[D]efinitional questions will arise about results that are neither clearly 'analytically valid' nor invalid, but of indeterminate validity. Results may range significantly in the precise degree to which they identify a characteris-

bility for both ends of the spectrum—the return of incidental findings or the failure to return incidental findings.[84]

Requiring researchers to return incidental findings to participants also raises serious concerns about therapeutic misconception.[85] Although a consistent definition has not been established,[86] therapeutic misconception occurs "when a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures."[87] In the case of genetics and genomics research, returning certain incidental findings, especially those with ambiguous or unknown significance, arguably causes "unnecessary scares" and violates the ethical obligation to minimize harm to research participants.[88] The risk for therapeutic misconception makes the need for legal clarity especially important for genetics and genomics researchers.[89] More research is needed to see whether and to what extent return of results creates a therapeutic misconception, but the concern should be considered when addressing the ethical and legal obligations of genetic and genomic researchers.[90]

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tic—that is, their predictive value.").

84. *See* Pike et al., *supra* note 12, at 812–13 ("This gap between the emerging majority view that some [incidental findings] ought to be returned and the reality that [incidental findings] often are not returned . . . has led to growing concern about potential legal liability . . . . [T]here is a growing sense that we may be standing at the precipice of legal liability . . . ."); *cf.* Gary E. Marchant & Rachel A. Lindor, *Personalized Medicine and Genetic Malpractice*, 15 GENETICS MED. 921, 921 (2013) ("[W]hen a new technology such as genetic testing is taken up . . . unevenly, a gap develops between the care provided by early adopters versus that by late adopters, again providing an opening for liability based on the disparity in treatment, with both early adopters and late adopters facing potential risk for being too quick or not quick enough to adopt the new technology.").

85. *See* Clayton & McGuire, *supra* note 14, at 474.

86. *See* Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735, 1735 (2007).

87. Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE 55, 57 (2002).

88. Ellen W. Clayton & Lainie F. Ross, Letter to the Editor, *Implications of Disclosing Individual Results of Clinical Research*, 295 J. AM. MED. ASS'N 37, 37 (2006).

89. *See* Alessi, *supra* note 26, at 1712–13 ("[A]n 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 results be narrowly drawn so as not to place a burden on researchers that will only undermine the research it aims to promote.").

90. *See* Clayton & McGuire, *supra* note 14, at 474 (explaining that the issue of therapeutic misconception "deserves further study").

C. RETURN OF INCIDENTAL FINDINGS AND COST CONSIDERATIONS

The ethical and legal ambiguity surrounding return of incidental findings raises several cost concerns for genetics and genomics researchers.[91] Numerous commentators have expressed anxiety that a legal duty to return incidental findings or individual research results will overly burden the research enterprise and threaten the ultimate purpose of medical research.[92] The potential cost implications of a duty to return incidental findings to research participants can be significant and requires more consideration.[93]

One significant cost of returning incidental findings is the cost of assuring that the results are analytically valid, clinically valid, and actionable. It is clear that disclosing incidental findings imposes costs on the research enterprise.[94] Prior to disclosing incidental findings to participants, researchers must verify and evaluate the findings to prevent disclosure of mistaken or misleading data, which would harm the participant by causing undue anxiety and unnecessary testing.[95] The costs—including time, money, and resources—of determining the validity and significance of the results, confirming these results, and providing adequate follow up and counseling can be extremely bur-

91. *See generally* Conrad V. Fernandez et al., *Considerations and Costs of Disclosing Study Findings to Research Participants*, 170 CAN. MED. ASS'N J. 1417, 1417 (2004) (discussing the costs of disclosure as three broad categories: risk associated with the procedures, consequences of disclosure, and logistics of the study); Kathryn A. Phillips et al., *Is the "$1000 Genome" Really $1000? Understanding the Full Benefits and Costs of Genomic Sequencing*, 23 TECH. & HEALTH CARE 373 (2015).

92. *See* Miller et al., *supra* note 31, at 278 ("As a general principle, the scope of the responsibility for incidental findings should be assessed in light of the potential impact on the primary mission of research, which is to promote socially valuable, generalizable knowledge."); Pilar N. Ossorio, *Letting the Gene Out of the Bottle: A Comment on Returning Individual Research Results to Participants*, 6 AM. J. BIOETHICS 24, 25 (2006) ("If offering individual results becomes the norm, I fear that we will sacrifice a tremendous amount of research . . . ."); *cf.* Bledsoe et al., *supra* note 9, at 104 (arguing that in the context of biobanks, "the costs and burdens to the research enterprise more broadly could be enormous and one cost to society could be inhibiting important research").

93. *See* Parens et al., *supra* note 8 ("Our approaches have to take into account the real costs associated with generating and reporting such information . . . ."); Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 364–65 ("Striking the right balance between necessary management of [incidental findings] and containment of research costs will be important.").

94. *See* Pike et al., *supra* note 12, at 802.

95. *See* Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 376.

densome on the research enterprise.[96]

Disclosing incidental findings may also impose significant costs by requiring researchers to obtain meaningful informed consent. Researchers are required to obtain informed consent from research participants.[97] If researchers are required to return or at least offer to return incidental findings, this could drastically change the process of receiving informed consent. Researchers will likely struggle to provide participants enough information to allow participants to give meaningful informed consent.[98] Some commentators fear that the cost of acquiring consent and returning incidental findings could "hobble . . . critical areas of research."[99] Obtaining informed consent could present a significant cost[100] for researchers who face a duty to return incidental findings and these costs should be considered when determining researchers' duties to participants.

Besides the cost of obtaining informed consent, the act of returning the incidental results is difficult and costly.[101] Genetics and genomics information is difficult to explain to participants and this task becomes even more difficult when the implications of genetic information are unknown or unclear.[102] Sometimes, the researchers are not the most qualified to share the incidental findings because they may lack the skill and knowledge to convey the results in a meaningful and under-

96. *See* Pilar Ossorio, *Taking Aims Seriously: Repository Research and Limits on the Duty To Return Individual Research Findings*, 14 GENETICS MED. 461, 464 (2012) ("The burdens and costs of returning individual IFs and RRs—including money, people's time, and the opportunity cost of not doing more research because one is engaged in returning information to contributors—aggregate swiftly."). *See generally* Ulrich, *supra* note 18, at 132 (discussing the minimum requirements for returning results to participants).

97. 45 C.F.R. § 46.116 (2014). The National Human Genome Research Institute defines "informed consent" as "[a] voluntary agreement to participate in human subjects research . . . based on adequate knowledge and understanding." *Informed Consent for Genomics Research*: *Glossary*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/27559022 (last visited Nov. 30, 2015).

98. *See* Beskow & Burke, *supra* note 7 ("[I]t is difficult to imagine how participants could be given enough information to make a fully informed decision . . . .").

99. Clayton & McGuire, *supra* note 14, at 475.

100. *See, e.g.*, *id*. (explaining that the Centers for Disease Control and Prevention decided to forego genetic research as the "cost of obtaining adequate consent was estimated to be in the millions of dollars").

101. *See* Bledsoe et al., *supra* note 9 ("Delivering genetic information is costly and complex.").

102. *See* Clayton & McGuire, *supra* note 14, at 476 ("Helping people understand complex, probabilistic information is hard enough; it becomes much more difficult when that information is new and its clinical impact is not clear.").

standable way to the participant.[103] Researchers may need help returning incidental findings and this may impose more costs on researchers by requiring them to hire additional staff or spend more time explaining these results.

As stated above, researchers facing an ethical obligation to return incidental findings may face future legal liability if that ethical obligation morphs into a legal obligation. Legal obligations will undoubtedly lead to increased costs for researchers.[104] Arguably, once a standard of care is established, the standard is likely to persist.[105] Furthermore, researchers may be motivated to continue to return incidental findings, as a form of "defensive research," analogous to the practice of defensive medicine by physicians.[106] The mere threat of liability may drive researchers' behavior and impose additional burdens on the research enterprise.[107]

While many commentators discuss the costs that researchers may face when returning incidental findings, some commentators also discuss the potential implications for the health care system. Clayton and McGuire referred to this as the "largely unspoken concern."[108] Drawing a parallel to the clinical context, Clayton and McGuire argue that returning incidental findings may increase health care costs, both for the individual and society at large, because these findings will potentially lead to downstream tests and side effects.[109] Clayton and McGuire provide a helpful example of variants in HFE, the gene associated with hemochromatosis.[110] Arguably, these results of variants should not be shared when uncovered in research because population-based screening for the same variants was rejected as not cost effective because the variants were poorly pene-

103. *See* Sharon F. Terry, *The Tension Between Policy and Practice in Returning Research Results and Incidental Findings in Genomic Biobank Research*, 13 MINN. J.L. SCI. & TECH. 691, 721–22 (2012).

104. *See* Ulrich, *supra* note 18, at 134 (arguing that "potential downstream cost of researcher liability could evolve from creating an ethical duty").

105. *See* Price, *supra* note 77 (explaining that once a legal duty is established, the duty will continue in the long term "because the legal standard of care is generally a one-way ratchet to which requirements may be added but only rarely removed").

106. *Id.* at 49.

107. *See* Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 366 (emphasizing that the "fear of legal liability should not drive the evolution of duties").

108. Clayton & McGuire, *supra* note 14, at 475.

109. *Id.*; *see also* Terry, *supra* note 103, at 721.

110. Clayton & McGuire, *supra* note 14, at 475.

trant.[111]

While returning results imposes costs, not returning results can also be costly. Most literature fails to address this aspect of cost to return, but the tangible and intangible costs of not returning incidental findings to participants can be detrimental to society as well as the research enterprise. First, not returning incidental findings can be harmful to society through increased demands on the health care system. If a researcher returns an incidental finding to a participant, this individual may be able to take preventative steps to avoid future health care costs. Thus, by not returning their findings, researchers may deprive participants of the opportunity to take these steps and avoid increased health care costs in the future.[112] Second, not returning results can lead to intangible costs that are difficult to quantify, but could threaten the public perception of genomics and genetics research. Society's loss of trust and the perceived lack of reciprocity[113] could lead individuals to forego participating in genomics and genetics research. Although these costs are difficult to calculate, these negative implications should also be considered when determining whether incidental findings should be offered to participants.

Given the extent and scope of these potential costs,[114] plus recent budget concerns, the legal ambiguity surrounding researchers' duty to return incidental findings to participants presents compounding problems for researchers.[115] The goal of

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111. *Id.*

112. The cost-effectiveness of preventative care raises its own debates and criticisms that go beyond the scope of this Note. *See generally* Joshua T. Cohen et al., *Does Preventative Care Save Money? Health Economics and the Presidential Candidates*, 358 NEW ENG. J. MED. 661, 661 (2008) ("Studies have concluded that preventing illness can in some cases save money but in other cases can add to health care costs.").

113. *See* Jennifer Viberg et al., *Incidental Findings: The Time Is Not Yet Ripe for a Policy for Biobanks*, 22 EUR. J. HUM. GENETICS 437, 438 (2014) ("[Reciprocity] holds that people deserve something in return for their contribution . . . . It may also be argued that research would benefit from disclosing individual research results to participants; because offering something in return might motivate participation . . . [and] could be useful in recruiting and retaining research participants." (citations omitted)).

114. Calculating these costs presents a significant hurdle that further research will need to address. *See* Terry, *supra* note 103, at 720 ("In a climate of evolving technology, data aggregation, and societal interest in genetic information, it is difficult to determine the weight of benefits and risks."); Susan M. Wolf, Letter to the Editor, *Return of Results in Genomic Biobank Research: Ethics Matters*, 15 GENETICS MED. 157, 158 (2013) ("Quantifying the cost of handling [individual research results] and [incidental findings] will not be easy.").

115. *See, e.g.*, Beskow & Burke, *supra* note 7, at 4 ("In some contexts, the

medical research is to benefit society as a whole, rather than the individual participants, so the costs imposed on the research enterprise should be included in the calculus to determine and clarify the ethical and legal obligations of researchers to return incidental findings.

II. ANALYZING POTENTIAL COSTS OF RETURNING INCIDENTAL FINDINGS

A duty to disclose incidental findings, whether ethical or legal, is costly. Returning those findings is costly. The reality is that medical researchers are faced with tradeoffs. Researchers have limited funding and scarce resources. These scarce resources need to be allocated efficiently in order to advance the goal of medical research, which is the pursuit of generalizable knowledge that benefits society as a whole. Returning incidental findings has the ultimate effect of diverting money, time, and researchers away from actual research. This Note does not argue that incidental findings should never be returned to participants, but it does strive to point out the need for research, discussion, and consideration of the cost implications of returning incidental findings in genetics and genomics research. Section A addresses what incidental findings should be offered to participants. Section B discusses who should offer to return the results. Section C analyzes who should pay to return incidental findings, while Section D looks at how long a potential duty to return findings could last. Finally, Section E summarizes the potential costs of not returning incidental findings to research participants.

A. WHAT SHOULD BE RETURNED?

A good starting point for this analysis is looking at what findings should be returned, which is not an easy question to answer. The question encompasses several other issues, including informed consent, verification of the results, the scope of the results that should be returned, and the scope of a researcher's duty to search for incidental findings buried in their results. This Note will address each of these issues in turn.

The most recent recommendations for returning incidental findings were published in 2014 by the Clinical Sequencing Ex-

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rationale for providing individual results is insufficient to justify spending scarce research resources to do so."); Klitzman, *supra* note 83 ("[R]esearch resources are already limited, given budgetary constraints at the National Institutes of Health . . . yet the costs of testing and counseling can be very high.").

ploratory Research (CSER) Consortium and the Electronic Medical Records and Genomics (eMERGE) Network working group.[116] The working group delineated a floor and a ceiling for returning research results.[117] The working group also set forth five guiding principles and discussed remaining areas of controversy.[118] Using these recommendations as a starting point, this Section will address remaining questions related to obtaining informed consent, verifying the validity of results, determining the scope of results that should be returned, and addressing the duty to search.

1. Informed Consent

The issue of what to return to research participants starts with consent. In other words, what has the participant said about his or her desire to receive potential incidental findings. The Common Rule requires that researchers obtain "legally effective informed consent" from the research participant.[119] The need for informed consent and what constitutes informed consent has generated considerable debate, some of which goes beyond the scope of this Note, in the genetics and genomics research community.

Consent is very much relevant to the potential costs imposed on researchers.[120] For genetics or genomics research, genetic counselors are needed to provide the necessary information to allow participants to give adequate informed consent.[121] The role of genetic counseling is to help people understand the medical and psychological implications of genetic and genomic contributions to disease.[122] Because of their short

116. Jarvik et al., *supra* note 18.

117. *Id.* at 821 (defining the floor "as the return of well-established, important actionable genetic findings relevant to the intent of the research study or uncovered in the course of usual research procedures" and the ceiling "as the entire genome sequence or some representation of it").

118. *Id.*

119. 45 C.F.R. § 46.116 (2014).

120. *See* Clayton & McGuire, *supra* note 14, at 475 (providing an example of one study in which attaining adequate consent would cost millions of dollars).

121. *See* Ulrich, *supra* note 18, at 132. *But see* Paul S. Appelbaum et al., *Models of Consent to Return of Incidental Findings in Genomic Research* 44, HASTINGS CTR. REP. 22, 24, 27 (2014) (outlining four different models of consent to return of incidental findings and concluding that "[n]one of the possible models for informed consent to return of incidental findings in genomic research is ideal").

122. Barbara Bernhardt, *Genetic Counselors and the Future of Clinical Genomics*, 6 GENOME MED. 49, 49 (2014). Helping participants understand potential implications of genomic sequencing is a complicated process that re-

supply, genetic counselors are usually quite expensive.[123] In addition to genetic counselors, most commentators agree that consent forms should address the possibility of incidental findings.[124] Besides the ethical and legal justifications for providing this information, the cost of reconsent provides additional support for consent prior to the start of the research study. Reconsent is the process of recontacting the participant to receive their consent for additional use of their information[125] or the potential return of results that had not been addressed in the prior consent process.[126] Two recent studies have calculated the average cost of reconsent to be approximately $50 per individual.[127] These costs are likely to vary depending on the method of reconsent.

Related to the issues of consent and reconsent, many ethicists argue that a person has a right not to know one's own

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quires tempering participants' expectations, educating participants about the limitations of genomic sequencing and genetic testing, and explaining the uncertainty of some potential results. *Id.* at 50. A recent study interviewed twenty-nine genetic counselors and research coordinators about their experiences with obtaining informed consent for genomic sequencing, highlighting the challenges with participant understanding and managing participant expectations. Ashley N. Tomlinson et al., *"Not Tied up Neatly with a Bow": Professionals' Challenging Cases in Informed Consent for Genomic Sequencing*, J. GENETIC COUNSELING (forthcoming 2016) ("He had highlighted the consent form very carefully and he highlighted the word 'genome' and he kept saying 'gnome' . . . he was like 'What's a gnome? What does that mean? . . . Is that in my body? Can you take it out of me?'").

123. *See* Klitzman, *supra* note 83 ("Genetic counselors are already in short supply."); Ulrich, *supra* note 18, at 133.

124. *See* Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 374 (arguing that a process must be in place to review the informed consent plan to ensure that potential participants are aware of the possibility of incidental findings and whether and when this information will be offered); Wolf et al., *Managing Incidental Findings*, *supra* note 8, at 228.

125. Michele L. Cote et al., *Re-contacting Participants for Inclusion in the Database of Genotypes and Phenotypes (dbGaP): Findings from Three Case-Control Studies of Lung Cancer*, 6 GENOME MED. 54, 54 (2014).

126. *See* Paul S. Appelbaum et al., *Researchers' Views on Informed Consent for Return of Secondary Results in Genomic Research*, 17 GENETICS MED. 644, 645 (2014) (describing a staged consent process in which there is a "brief mention of secondary findings at the time of initial consent but with more detailed consent for return of specific findings obtained if and when reportable results are found").

127. Cote et al., *supra* note 125, at 57 (estimating the total cost of reconsent to be the annual salary of one full-time interviewer, which resulted in approximately $47.60 per individual); Evette J. Ludman et al., *Glad You Asked: Participants' Opinions of Re-Consent for dbGaP Data Submission*, 5 J. EMPIRICAL HUM. RES. ETHICS 9, 15 (2010) (finding that cost of seeking reconsent was approximately $50 per participant).

genes or genomic sequence[128] and if they do not consent to the return of genetic and genomic research results or incidental findings, then the researcher should not return anything. Indeed, one of the working group's principles states that participants should have the right to refuse any results that are offered.[129] Thus, once a participant has denied consent to the return of research results or incidental findings, the researcher cannot offer to return any result to the participant.

2. Verifying the Analytical Validity of the Results

Another looming issue is whether the results must be verified in a CLIA-certified lab[130] before being returned to the participant. As Gail P. Jarvik and her colleagues point out, this is still an area of controversy.[131] Before offering results to a participant, researchers must verify that their findings are analytically valid[132] to prevent false reporting and potential harm to participants. Some contend that this requires the results to be tested in a CLIA-certified lab.[133] Arguably, requiring results to be CLIA certified would reduce the likelihood of returning inaccurate results. Inaccurate results could lead to unnecessary follow-up tests for the participant, increased costs for participants and the health care system, and stress on the participant and others. Most research labs, however, are not CLIA-certified labs.[134] Requiring CLIA certification could be costly to researchers.[135] In some cases, CLIA certification of research results may

128. For more discussion on the debate over one's right not to know in the research context, see Gert Helgesson, *Autonomy, the Right Not To Know, and the Right To Know Personal Research Results: What Rights Are There, and Who Should Decide About Exceptions?*, 42 J.L. MED. & ETHICS 28 (2014).

129. Jarvik et al., *supra* note 18.

130. Clinical Laboratory Improvement Amendments (CLIA) is a federal statute that dictates the certification and oversight of clinical laboratory testing. Certification of Laboratories, 42 U.S.C. § 263a (2012). A CLIA-certified lab is a lab that is in compliance with the CLIA regulations.

131. Jarvik et al., *supra* note 18, at 822.

132. Lisa Eckstein et al., *A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings*, 42 J.L. MED. ETHICS 190, 194 (2014) ("The accuracy of predictions about a genetic variant's presence or absence in a research participant is at the heart of most definitions of analytic validity.").

133. *See, e.g.*, Vardit Ravitsky & Benjamin S. Wilfond, *Disclosing Individual Genetic Results to Research Participants*, 6 AM. J. BIOETHICS 8, 10 (2006).

134. Ellen Wright Clayton, *Incidental Findings in Genetics Research Using Archived DNA*, 36 J.L. MED. & ETHICS 286, 290 (2008) ("Most research laboratories do not adhere to CLIA requirements . . . .").

135. Black et al., *supra* note 26, at 403 (arguing that such confirmatory testing "will inevitably increase the costs of IF disclosure"); Klitzman, *supra* note 83 ("Repeated tests through Clinical Laboratory Improvement Amend-

be impossible.[136] Some argue that if the results cannot be CLIA certified, then participants should be informed of this at the time of return and should be recommended to have the results verified by a CLIA-certified lab.[137]

Even if the results cannot be verified by a CLIA-certified lab, researchers still have a responsibility to confirm the analytical validity of the results.[138] Whether researchers verify their results through a CLIA-certified lab or by some other means,[139] researchers must bear some costs to ensure that findings offered to participants are accurate. This cost is unavoidable for researchers, who must prevent harm or undue stress on research participants and comply with ethical and legal mandates.

3. Scope of Incidental Findings that Should Be Offered to Participants

Assuming valid informed consent was given and the results are adequately confirmed, what information should be offered to a participant? At the extremes of the spectrum of incidental findings to offer, researchers could offer to return nothing or offer to return everything. While returning nothing may seem advantageous because it minimizes the cost and burden of interpreting and returning incidental findings, most researchers have rejected this approach as being ethically unsupportable.[140]

On the other end of the spectrum is the offer to return everything. Although some argue that this approach may be very beneficial for the research community by affirming the value of research participation and building trust in the research enterprise,[141] this approach is likely to be overly costly and burdensome on researchers and some results may arguably violate the Common Rule by harming participants with the return of re-

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ments (CLIA)-certified labs can also be expensive.").

136. Jarvik et al., *supra* note 18, at 823 (explaining that "research circumstances might make a CLIA-compliant test impossible").

137. *See* Wolf et al., *Managing Incidental Findings*, *supra* note 8, at 231.

138. It is important to note that analytical validity is distinct from clinical validity. *See id.*

139. For examples of other means to verify analytical validity, see Eckstein et al., *supra* note 132.

140. *See* Pike et al., *supra* note 12, at 833.

141. *See* Laura M. Beskow et al., *Offering Aggregate Results to Participants in Genomic Research: Opportunities and Challenges*, 14 GENETICS MED. 490, 491–92 (2012).

sults that have unknown significance.[142] Furthermore, this approach may blur the lines of clinical care and medical research and could, thus, contribute to therapeutic misconception.[143]

Rather than selecting one of the two extremes, Jarvik and colleagues state that "analytically and clinically valid information that is of an important and actionable medical nature and that is identified as part of the research process should be offered to a research participant."[144] Essentially, when researchers have a valid research result for which the participant can take preventative measures to protect his or her health, then researchers should offer this result to the participant.[145] This general principle breaks down, however, when policymakers try to define "actionable."[146]

The definition of "actionable" varies by research study and context.[147] One clear example of this is in a research study for children. Should the child or the child's parents be offered results of adult-onset findings?[148] Historically, the answer has been no.[149] Some commentators argue, however, that these findings are actionable and should be returned.[150]

The danger of an ambiguous definition of "actionable" leads to liability concerns down the road. If researchers fear that they will be sued for not returning an "actionable" result, then they may choose to return everything or more than they should. As seen above, returning too much information can lead to negative consequences and impose costs on researchers and participants.

Given the ambiguity of how to define "actionable," it is dif-

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142. *Id.* at 492–93; Pike et al., *supra* note 12, at 835.

143. Beskow et al., *supra* note 141, at 493.

144. Jarvik et al., *supra* note 18.

145. *Id.* at 821.

146. *Id.* ("The definition of what is actionable is a matter of judgment.").

147. Richard R. Fabsitz et al., *Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants: Updated Guidelines from a National Heart, Lung, and Blood Institute Working Group*, 3 CIRCULATION CARDIOVASCULAR GENETICS 574, 575–76 (2010) ("Actionable means that disclosure has the potential to lead to an improved health outcome . . . . Actionable may include surveillance and interventions to improve clinical course, such as by delaying onset, leading to earlier diagnosis, increasing likelihood of less burdensome disease, or expanding treatment options.").

148. Jarvik et al., *supra* note 18, at 821.

149. *Id.*

150. *See id.*; *cf.* Robert C. Green, *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS MED. 565, 568 (2013) (recommending that searching for and returning findings should not be limited by the age of the participant in the clinical setting).

ficult for researchers to predict how many actionable incidental findings they may recover. Several studies have looked into the likelihood of identifying incidental findings. Lucy-Enid Ding and colleagues published a study in 2014 looking at a screening panel of 24 conditions.[151] They found that approximately 2.7% of screened individuals would have an incidental finding.[152] Michael O. Dorschner and colleagues performed a study in 2013 to determine the likelihood of identifying actionable findings.[153] Christopher A. Cassa and co-authors found a rate of 6.88% of participants having an incidental finding that was recommended for disclosure.[154] But, Yali Xue and colleagues reported 11% of 179 screened individuals had an incidental finding.[155] These studies illustrate the challenge for researchers to predict the potential number of actionable incidental findings.[156] Without being able to reasonably predict the number of actionable incidental findings, researchers will struggle to predict the costs to return such results.

4. Costs Associated with a Potential Duty To Search

Finally, if researchers have a responsibility to return some research results to participants, does this responsibility require researchers to search for results buried in one's genome? Jarvik and colleagues recommend that research resources should be primarily used for scientific discovery and, thus, researchers do not have a duty to search for findings.[157] Such a duty is likely to be costly and overly burdensome for researchers.[158]

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151. Lucy-Enid Ding et al., *The Impact of Reporting Incidental Findings from Exome and Whole-Genome Sequencing: Predicted Frequencies Based on Modeling*, 17 GENETICS MED. 197, 197 (2015).

152. *Id.* at 198.

153. Michael O. Dorschner et al., *Actionable, Pathogenic Incidental Findings in 1,000 Participants' Exomes*, 93 AM. J. HUMAN GENETICS 631, 631 (2013).

154. Christopher A. Cassa et al., *Disclosing Pathogenic Genetic Variants to Research Participants: Quantifying an Emerging Ethical Responsibility*, 22 GENOME RES. 421, 423 (2012).

155. Yali Xue et al., *Deleterious- and Disease-Allele Prevalence in Healthy Individuals: Insights from Current Predictions, Mutation Databases, and Population-Scale Resequencing*, 91 AM. J. HUM. GENETICS 1022, 1030 (2012).

156. *See also* Julia Karow, *As Labs Start Returning Incidental Findings, Weighing Variant Pathogenicity Remains Challenge*, GENOME WEB (May 14, 2014), https://www.genomeweb.com/sequencing/labs-start-returning-incidental-findings-weighing-variant-pathogenicity-remains ("The lack of clear criteria for classifying variants as pathogenic likely leads to differences in incidental findings rates between laboratories . . . .").

157. Jarvik et al., *supra* note 18.

158. *See* Wolf et al., *Law of Incidental Findings*, *supra* note 39, at 376.

In 2013, Catherine Gliwa and Benjamin E. Berkman evaluated the benefits and costs of a duty to search.[159] Gliwa and Berkman conclude that researchers have no duty to search, relying in part on the costs that would be imposed on researchers.[160] Prior to any filtering, researchers would be faced with approximately 80,000 variants per exome or 3 to 4 million variants of each genome for each participant.[161] Next, researchers would filter these results to leave only those variants that are most likely to cause disease.[162] Then, researchers must determine whether a specific variant is likely to cause disease, but this is a tedious process that must be done manually.[163] Considerable time, resources, and money are needed to perform such an analysis.

In addition, many commentators and policymakers fear that an ethical duty to search may evolve into a legal duty.[164] Given the costs and resources required to satisfy a duty to search, the threat of legal liability for failure to search could have the negative consequence of driving researchers out of doing research as the costs of research may not justify the benefits.

Issues about what incidental findings to offer to research participants and the costs of offering these results are extremely complex and can have serious legal implications. Issues of informed consent, analytical validation, which results should be returned, and potential duties to search illustrate the complexity of returning incidental findings to participants. These issues and how they are resolved have significant consequences for both researchers and participants and thus require careful consideration by policymakers and those drafting recommendations.

B. WHO SHOULD RETURN?

Who should return the results is another area that raises cost and legality concerns. At first glance it may seem obvious to have the researchers return the results. The researchers designed the study. The researchers recruited the participants.

159. Gliwa & Berkman, *supra* note 61, at 32.

160. *Id.* at 41.

161. *Id.* at 37; *see* Leslie G. Biesecker, *Opportunities and Challenges for the Integration of Massively Parallel Genomic Sequencing into Clinical Practice: Lessons from the ClinSeq Project*, 14 GENETICS MED. 393, 394 (2012).

162. Gliwa & Berkman, *supra* note 61, at 37.

163. *Id.*

164. *See* Price, *supra* note 77, at 49.

The researchers performed the genetic tests or genomic sequencing. The researchers found the incidental finding. In *Grimes*, the court held that researchers have a "special relationship" with their participants[165] and this could be interpreted to mean that researchers should be the ones to offer to return results to participants. But it is important to remember that the researchers discovered an incidental finding, something they were not looking for. The researchers may have no knowledge of the significance of a particular variant, how to interpret the variant, or what the variant might mean (if anything).[166] The method of returning results remains an area of contention and in need of further research.[167]

One method proposed is that the researcher bears the responsibility to return incidental findings to participants. Returning genomic or genetic results in an ethical manner requires time and resources. Explaining genomic and genetic test results is very complex.[168] If the results yield novel findings or have unknown significance, returning and explaining these results becomes exponentially more difficult.[169] The danger of misinterpretation or miscommunication is significant. The threat of misinterpretation may not be enough to justify no return of findings, but it highlights the challenge facing researchers who have to explain these results to a participant. These challenges increase the amount of time, resources, and money that need to be diverted from other areas of the research budget.[170] In a recent study, researchers determined that to disclose results to research participants cost $68 and required 78 minutes on average.[171] These calculations are likely to vary considerably depending on the type of study.[172]

If the researcher has the responsibility to return and explain the incidental findings, the researcher may need to hire

165. Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 834–35 (Md. 2001).

166. *See* Black et al., *supra* note 26, at 401 ("Variance on who should disclose [incidental findings] persists, and there is no clear overlap or consensus in the guidance."); Jarvik et al., *supra* note 18 ("[S]ome investigative teams are not qualified to interpret and/or return the results.").

167. Jarvik et al., *supra* note 18, at 823.

168. *See* Clayton & McGuire, *supra* note 14, at 476.

169. *Id.*

170. *See* Black et al., *supra* note 26, at 402 (explaining that researchers may not have the "required time to prepare for and perform the disclosure").

171. Kurt D. Christensen et al., *Disclosing Individual CDKN2A Research Results to Melanoma Survivors: Interest, Impact, and Demands on Researchers*, 20 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 522, 522 (2011).

172. *See id.* at 527–28.

additional personnel to do so.[173] Because researchers may not be the most qualified to return the results, additional genetic counselors or the participant's clinician may need to be involved in the disclosure. Even if the researcher is qualified to return the results, the researcher may not have the time to return the results. Regardless of the reason, hiring additional personnel will increase research costs.

Some also fear that requiring the researchers to return the results will blur the lines between clinical and research and could lead to therapeutic misconception.[174] Returning results can lead participants to believe that researchers will provide certain results or all results. Therapeutic misconception can lead to negative consequences as participants who expect to receive certain results, even if they were informed that they would not receive such results, may feel betrayed or cheated when they do not receive those results.[175] This could lead to serious implications for medical research as individuals begin to distrust the research enterprise or if participants feel they are being mistreated or disrespected. The potential negative stigma caused by therapeutic misconception is difficult to quantify into tangible costs.

While no explicit statute or court case imposes legal liability on researchers to return results, the potential for future liability should cause policymakers to consider these possible downstream consequences and consider the costs when proposing policy guidelines. Who returns the results is an important consideration from an ethical, legal, cost, and efficiency standpoint.

C. WHO PAYS?

Returning incidental findings to research participants can be a costly endeavor. Deciding who will bear these costs has important implications. Some argue that these costs should be included in the research budget.[176] While this may seem like an

173. *See id.* at 528.

174. *See* Alessi, *supra* note 26, at 1712; *cf. supra* notes 85–90 and accompanying text.

175. *See* Alessi, *supra* note 26, at 1711–12.

176. *See, e.g.*, Fernandez et al., *supra* note 91, at 1419 ("Researchers and granting agencies should consider the offer to return results to research participants as a mandatory part of practice and adjust budgets and duration of funding accordingly."); Wolf et al., *Managing Incidental Findings*, *supra* note 8, at 237 ("The cost of compensating the consultant for [incidental findings] verification and evaluation should be built into the research budget. . . . Agencies funding research should support this expense as a cost of performing re-

easy solution, making researchers bear more costs could have a significant impact on the research enterprise and future research projects.

First, given the complex issue of calculating the costs to return incidental findings, researchers will face a daunting challenge to predict the funding they will need to return results. The cost to return incidental findings is likely to vary substantially depending on a number of factors, including the design of the research study.[177] Ambiguity over what needs to be returned and how these results should be returned adds to this complexity. This likely adds costs as researchers try to determine what they must do to be ethically and legally compliant.

Assuming the current budget for medical research funding remains the same, as research projects require more funding, fewer projects will actually receive funding. Once again, society must face a trade-off between fewer research projects that receive more funding and return more incidental findings or more research projects that have less funding and return fewer findings.

Rising costs of medical research are especially alarming in light of recent budgetary concerns. The National Institutes of Health (NIH) funding ratio has been cut in half over the last decade.[178] While NIH and other granting agencies face less funding and researchers face increased costs, the result could be fewer genetics and genomics research projects being funded and long-term problems, such as researchers leaving the field or researchers moving away from genetics and genomics research.[179]

A recent study has found that Canadian participants would be willing to pay on average $445 to receive certain incidental findings from genomic sequencing.[180] The study also found that only 66% of participants would choose to receive these results.[181] While this may provide evidence that some costs may be shifted to the participants, the ethical or legal obligations of

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search ethically.").

177. *See* Fernandez et al., *supra* note 91 (listing three broad categories that affect the complexity of returning results).

178. Szabo, *supra* note 20.

179. *Id.*; *see also* Pomeroy & Kandel, *supra* note 23.

180. Dean A. Regier et al., *Societal Preferences for the Return of Incidental Findings from Clinical Genomic Sequencing: A Discrete-Choice Experiment,* 187 CAN. MED. ASSOC. J. 190, 195 (2015). These results were likely to have severe health consequences, but there was recommended effective medical treatment. *Id.*

181. *Id.*

requiring participants to pay for receiving incidental findings is unclear.

The threat of legal liability adds to genetics and genomics research concerns. Although no court has held a researcher liable for failure to return or improperly returning incidental findings, ethical recommendations can begin to evolve into legal standards of care. Requiring researchers to foot the bill for the cost to return and to face potential liability can have negative consequences on the research enterprise.

D. HOW LONG DOES THIS RESPONSIBILITY TO RETURN INCIDENTAL FINDINGS LAST?

If researchers have to return incidental findings to research participants, then researchers need to know how long they bear this responsibility. Jarvik and colleagues recommend that this responsibility last only during the period of funding to researchers.[182] They go on to say, however, that researchers may offer disclosure after the funding period ends.[183] Other commentators agree with Jarvik and her co-authors and argue that the responsibility to offer ends after the research project is over;[184] however, some do not explicitly limit the responsibility.

How long the responsibility lasts raises a question about the researchers' responsibility to recontact participants after the research project ends. Many commentators argue that such a duty would extend researchers' responsibilities beyond the responsibilities placed on clinicians. Clinicians are not required to monitor their patients' conditions continuously, but rather they respond to specific symptoms and situations when their patients come in for an appointment.[185] It is unusual for a clinician to recontact a patient based on new research.[186] So, to require a researcher to recontact would push the duties of a researcher beyond the duties that exist in clinical practice.[187]

Recontacting previous research participants can be costly and time-consuming.[188] A 2011 study led by Kurt D. Christensen and colleagues attempted to recontact 39 participants to disclose CDKN2A gene test results and implications for mela-

182. Jarvik et al., *supra* note 18, at 823.
183. *Id.*
184. *See, e.g.*, Fabsitz et al., *supra* note 147, at 577.
185. Clayton & McGuire, *supra* note 14, at 475.
186. *Id.*
187. *Id.* at 476.
188. *See, e.g.*, Deborah Levenson, *Legal, Ethical Issues Loom over Topic of Recontacting Patients*, 167 AM. J. GENETICS vii, vii (2015).

noma risk.[189] Per recontact attempt, the preparation to disclose the results cost $611 and required 40 minutes.[190] However, costs to recontact are likely to vary. In the 2011 study, the researchers attempting to recontact participants had access to experts in clinical genetics, genetic counseling, and other health experts.[191] This allowed the team to make specific recommendations for potential follow-up.[192] Christensen and colleagues note that "[r]esearchers lacking the same access to interdisciplinary expertise may need to seek institutional partners,"[193] which will likely add to the cost of recontact.

Issues of how long a researcher's responsibility to return results lasts and researchers' potential responsibilities to recontact participants raise cost and resource concerns. On one end of the spectrum, the researcher's responsibility could cease with the research study. On the other end, researchers may have duties that extend beyond the funding period and beyond those of clinicians. The issue of how long this responsibility extends is important for the legal issues it implicates. As ethical recommendations are adopted and standards of care are created, legal standards are likely to begin evolving. Eventually, the threat of liability and the costs of legal compliance may exceed the benefits or feasibility of performing genetics or genomics research, ethically and legally.

E. WHAT ARE THE COSTS OF NOT RETURNING INCIDENTAL FINDINGS?

While returning incidental findings is a costly endeavor, a researcher's failure to return an incidental finding can also impose costs on the health care system and the research enterprise. To illustrate these potential costs, one should return to the hypothetical in the introduction. If Sandy Cohen underwent genomic sequencing for research, but the researchers did not return her BRCA1 incidental finding, and Sandy discovers several years later that she has breast cancer—what are the implications for society and for the research enterprise?

One cost to society could be increased costs on the health care system. It is possible that if participants are given incidental findings then they could seek preventative treatment

189. Christensen et al., *supra* note 171.
190. *Id.* at 526–27.
191. *Id.* at 527.
192. *Id.* at 527–28.
193. *Id.* at 528.

that could avoid major costs down the road.[194] Delaying treatment can impose additional costs on the health care system due to additional testing; more drastic medical care, such as surgeries or operations that may have been preventable if the disease had been caught earlier; and increased hospital stays and treatment. These costs are very difficult to quantify, and it is not always clear that the incidental finding will provide an opportunity for preventative care or that a participant would undergo preventative care, even if the care were available.

Not only could not returning incidental findings lead to costs for society in general, but not returning findings can also lead to direct costs to the research enterprise. One such cost may be the loss of the public's trust in the research enterprise. Loss of trust can lead to fewer research participants.[195] Several studies have concluded that most participants want to know these research results[196] and may feel some entitlement to receive these results.[197] Thus, the failure to return incidental findings can lead to bad publicity for the research enterprise. Bad publicity, loss of trust, and lack of reciprocity may have cost implications for the research enterprise and may threaten the sustainability of genomics and genetics research as fewer individuals decide to participate in these studies. Although these costs are nearly impossible to quantify, the cost of not returning incidental findings should be considered as researchers determine what incidental findings should be returned to participants.

This Part has shown that offering to returning incidental

194. *See, e.g.*, Jolie, *supra* note 6 (describing Angelina Jolie's story of undergoing a preventative double mastectomy after her doctors discovered she had a BRCA1 mutation).

195. *Cf.* Beskow et al., *supra* note 141, at 492 (arguing that for scientists who maintain genomic biobanks, "trust . . . is essential to their continued existence").

196. *See, e.g.*, Caroline Savage Bennette et al., *Return of Incidental Findings in Genomic Medicine: Measuring What Patients Value—Development of an Instrument to Measure Preferences for Information from Next-Generation Testing (IMPRINT)*, 15 GENETICS MED. 873, 873 (2013) (investigating participants' preferences for incidental findings); Juli Murphy Bollinger et al., *Public Preferences Regarding the Return of Individual Genetic Research Results: Findings from a Qualitative Focus Group Study*, 14 GENETICS MED. 451, 452 (2012) (finding that most participants wanted their individual research results). *But see* Clayton & McGuire, *supra* note 14, at 474 ("It is also difficult to assess participants' general preferences regarding return of results when it is not clear what specific results might become available.").

197. *See* Bollinger et al., *supra* note 196, at 453 ("For many, the desire . . . appeared to be related to a sense of ownership, i.e., that information about their genes belongs to them.").

findings is costly on the research enterprise, but not offering to return these findings can also impose costs. Although many commentators cite costs of returning incidental findings as a major concern, these costs are not well understood and current data on the costs to offer incidental findings in genetics and genomics research is lacking. Until more data is available, however, genetics and genomics researchers find themselves in a difficult situation. With limited funding and scarce resources, genetics and genomics researchers need guidance to allocate resources efficiently while complying with their ethical and legal obligations. Part III of this Note proposes a responsible default rule and much-needed guidance to assist genetics and genomics researchers in their decision to offer or not offer incidental findings to research participants.

III. DEFINING AN ETHICALLY, LEGALLY, AND FISCALLY RESPONSIBLE DEFAULT RULE

Policymakers making ethical recommendations to medical researchers must consider the cost and legal implications of their recommendations. As analyzed above, the issue of returning incidental findings to research participants is a complex and multi-faceted problem. Questions about what should be returned, who should return results, who should pay for the returning, and how long a duty extends require serious consideration by policymakers. Any proposed recommendations for genetics and genomics researchers encompass ethical, legal, cost, and societal issues that require further research and evaluation. But, in the face of limited data and research on the cost of returning incidental findings to participants, policymakers need to give guidelines that allow researchers to fulfill the purpose of their research without overburdening the research enterprise. Sections A through E will address the distinct questions presented above as to what incidental findings should be returned, who should return the findings, who should pay, how long a duty to return should last, and what are the costs of not returning. Section F will provide a default rule and explain how this default places minimal burdens on researchers and provides much needed guidance and security from the threat of future legal liability.

A. WHAT INCIDENTAL FINDINGS SHOULD BE OFFERED WILL DEPEND ON THE RESEARCH STUDY

What results should be returned is a complex question that

encapsulates other complicated issues.[198] Informed consent, analytical verification of results, actionability of results, and the duty to search for incidental findings make it difficult for researchers to know what results should be offered to participants and what the cost of offering and returning those results will be. In general, policymakers should keep in mind that the goal of medical research is to produce generalizable knowledge.[199]

Federal regulations require researchers to acquire informed consent.[200] Although this is a costly process, it is required both ethically and legally.[201] Researchers should prepare their study in a way to ensure adequate informed consent, while still keeping the cost of informed consent manageable. Researchers should address the possibility of incidental findings with participants up front in order to prevent the cost of reconsent later. Informed consent may be costly, but because it is required, researchers must abide by the Common Rule while managing the costs of informed consent to avoid hobbling the research study budget.[202]

Whether research results must be verified in a CLIA-certified lab is also a complex issue facing researchers and one that requires more research.[203] But, whether CLIA certification is required does not negate the need for researchers to confirm the analytical validity of their results. This confirmation is needed to prevent undue harm to participants from false positives or other inaccurate results.[204] Like informed consent, analytical verification is not a cost that can be avoided but is rather a cost to be accounted for and managed.

Another issue facing genetics and genomics researchers is the difficulty of predicting how many incidental findings they may uncover in their research and whether these results are actionable.[205] While policymakers have published recommendations for what should be returned, issues surrounding actionability make these obligations less than clear. This ambiguity raises legal concerns as different standards of care can

198. *See supra* Part II.A.

199. *See* Ulrich, *supra* note 18, at 128.

200. Requirements for Informed Consent, 45 C.F.R. § 46.116 (2014).

201. *See supra* Part II.A.1.

202. *See* Clayton & McGuire, *supra* note 14, at 475.

203. *See supra* Part II.A.2.

204. Criteria for IRB Approval of Research, 45 C.F.R. § 46.111 (2014), requires that researchers minimize potential risks to participants.

205. *See supra* Part II.A.3.

evolve from different definitions of "actionable." Recognizing this danger, policymakers should leave it to researchers to decide what is actionable as this definition varies by context and research studies. Researchers should define what is actionable for the study and explain this to participants in the informed consent process. As long as researchers define actionability for their particular study and provide this information to participants, researchers should not be subjected to legal liability down the road for not adopting a different definition of actionability.

Finally, researchers should not have a duty to search or hunt for incidental findings. Such a duty would be overly burdensome and would push researchers' duties beyond the duties of clinicians, which have historically been more expansive than the duties of researchers.[206] An ethical duty to search for incidental findings would likely evolve into a legal duty, which will put more strain on the research enterprise. The benefits of searching for incidental findings should outweigh the costs of searching. While it looks like current costs are prohibitive, more research would help researchers and policymakers understand the implications of ethical recommendations to search.

B. WHO SHOULD OFFER TO RETURN INCIDENTAL FINDINGS MAY VARY BY STUDY

Who returns incidental findings to research participants is an important question that has potential legal ramifications as those who return the results may open themselves up to legal liability down the road if they fail to adequately return the incidental findings.[207] Unfortunately, given the variety of research study designs and researchers' expertise and knowledge in genetics and genomics, a one-size-fits-all approach is unlikely to be appropriate to resolve the question of who should return the results.

Researchers are likely to be the most qualified to determine their own resources and abilities to return incidental findings. Thus, researchers should address this issue prior to applying for funding. They should consider who can best bear the cost and responsibility of returning incidental findings while still providing participants with the information necessary to make informed choices about their health care. Whether the researchers offer to return the results or additional personnel are

206. *See* Clayton & McGuire, *supra* note 14, at 475–76.

207. *See supra* Part II.B.

hired for the task, researchers must ensure that they are giving participants adequate information while still managing the costs of the research project.

C. COSTS OF RETURNING INCIDENTAL FINDINGS ARE LIKELY TO FALL ONTO RESEARCHERS

Who should pay is an interesting question, because unlike in the medical profession, where costs are usually shifted to insurance companies, the research enterprise cannot always turn to insurers to cover additional costs. Researchers usually bear the costs of returning incidental findings to participants, meaning researchers either include the costs in their proposal for research funding or find other means by which to pay. Also, the cost to offer and return incidental findings is extremely difficult to calculate and thus, it is difficult for researchers to predict what costs they will face. As highlighted above, assigning the costs to researchers and the research enterprise could have a detrimental effect on the research enterprise. When giving ethical recommendations, policymakers need to remember that the costs to return incidental findings will likely be borne by researchers.

D. THE DUTY TO OFFER AND RETURN INCIDENTAL FINDINGS SHOULD BE LIMITED

A duty to return incidental findings should not extend past the research period. Furthermore, researchers should not have a duty to recontact participants to offer incidental findings. Researchers, however, should not be barred from recontacting prior research participants and offering to return results. But, researchers should be wary of doing so, as this could become the standard of care in the industry and could thus expose researchers to liability. Recontacting prior participants poses its own costs and challenges, and these challenges vary by research design and can be hard to predict.[208] Thus, policymakers should be explicit in their recommendations that researchers do not have a duty to return findings beyond the research period and have no duty to recontact participants.

E. THE COSTS OF NOT OFFERING AND RETURNING RESULTS MAY BE SIGNIFICANT

The costs of not returning should be included in the determination of whether to return incidental findings. First, the re-

208. *See supra* Part II.D.

searcher should look at what the potential is for an individual to use this information to prevent increased health care costs in the future.[209] Furthermore, researchers should be cognizant of how not returning findings can potentially lead to bad publicity for the research enterprise.[210] Bad publicity may result in reduced trust in the research enterprise and fewer individuals who are willing to participate in genetics and genomics research. These costs will likely depend on the actionability and pathogenicity[211] of the incidental finding and thus these factors should be taken into account.

F. A RESPONSIBLE DEFAULT FOR GENETICS AND GENOMICS RESEARCHERS

Several previous recommendations divide the decision to return into three bins: should return, may return, and should not return.[212] While this approach helps to provide some guidance to researchers, a default rule that recognizes and accounts for the cost implications of returning and not returning incidental findings is needed. A default rule should ensure that researchers satisfy their ethical responsibilities without imposing unnecessary threats of legal liability or overly burdening the research enterprise with unsustainable costs that will threaten the goal of genetics and genomics research—to "pursue generalizable knowledge that will benefit society."[213]

This proposed default rule requires that researchers offer to return the incidental findings to the research participant. But if the researcher weighs the costs and benefits of returning the results with the costs and benefits of not returning the incidental finding and concludes that the costs of returning the results outweighs the costs of not returning, then she should have no responsibility to offer the incidental finding to the participant.

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209. While this calculation is very similar to whether the incidental finding is actionable, this takes actionability and looks at it from the standpoint of society as a whole and how the return of an incidental finding can reduce costs on society, not just the participant.

210. *See supra* Part II.E.

211. Pathogenicity is the ability to cause a disease.

212. *See, e.g.*, Jonathan S. Berg et al., *Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time*, 13 GENETICS MED. 499, 501 (2011); Fabsitz et al., *supra* note 147, at 579.

213. Ulrich, *supra* note 18, at 128.

Figure 1. Decision to return scale: Weighing the costs and benefits to return or not return.

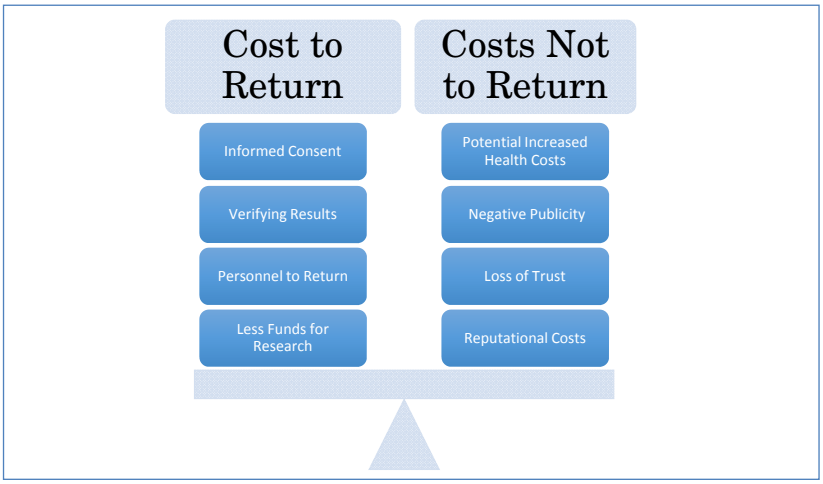

Figure 1 shows the weighing of the costs and benefits of the decision to return or not return incidental findings to research participants.[214] This approach takes into account the ethical, legal, and cost implications of returning or not returning incidental findings. Sometimes, the costs of returning due to lack of information about the actionability and the low benefit of possible preventive care will tip the scale to not return. Other times, however, the incidental finding may be easily verified and not overly burdensome to return, and by not returning the results, the researcher risks high reputational costs to the research enterprise, increased loss of trust, and increased future costs to the health care system. In these cases, the researcher should offer to return the incidental findings to the participant.

Weighing the costs and benefits on either side is not an easy task, but the researcher should merely have the burden of showing that her decision to return or not to return was reasonable. The researcher should, however, bear the burden because she is best equipped to make a determination as to whether it is better to return or not to return. Given the current legal system, researchers should not be surprised or overwhelmed by this burden, as the legal system often places the

214. Note that not all of the costs and benefit considerations are included in Figure 1. Figure 1 serves as a visual representation of how the balancing should work. Furthermore, these costs and benefits are fluid calculations that will likely vary significantly depending on the study.

burden on the party that has the most information and has the best ability to make an informed decision.[215]

This default rule not only provides much needed guidance to researchers, but it may also provide security from the threat of legal liability. If courts begin to allow negligence claims against researchers for failure to offer incidental findings, this default rule will provide strong evidence that the researcher was reasonable in her decision not to offer incidental findings. The default rule provides a process by which the researcher can show that she weighed the costs and benefits of returning and not returning incidental findings to research participants, and, thus, her decision not to return the findings was not based on a negligent act, but rather a well-informed, reasonably grounded basis.

CONCLUSION

Returning incidental findings to research participants, like Sandy Cohen, continues to be a hotly contested issue. Although no federal or state laws currently regulate the disclosure of these findings, the threat of legal liability is growing as more lawsuits are being brought against researchers, and as ethical recommendations are published and begin to establish a standard of care. The cost implications of the legal liability and the ambiguity surrounding potential liability raise serious concerns for researchers and society as a whole as the goal of medical research is to promote the benefit of society through the discovery of scientific, generalizable knowledge.

Policymakers need to recognize the potential for legal liability and need to consider the purpose of genetics and genomics research and the costs imposed on researchers by requiring disclosure of incidental findings. The cost of this duty is difficult to calculate and will likely vary substantially depending on the particular study. This Note illuminates the urgent need for more empirical research on the costs implicated by returning incidental findings in genomics and genetics research. Furthermore, this Note provides an ethically, legally, and fiscally responsible default rule for the return of incidental findings. The default rule places a minimal burden on researchers and also provides guidance and a sense of security from the

215. *Cf.* RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT LIABILITY § 8 (AM. LAW INST. 2000) ("Factors assigning percentages of responsibility . . . include (a) the nature of the person's risk-creating conduct, including any awareness or indifference with respect to the risks created by the conduct . . . .").

threat of future legal liability.