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Non-Consensual Disclosures

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Non-Consensual Disclosures

Nina Varsava*

In the course of biomedical research on humans – for example, flu, imaging, and genomic studies – researchers often uncover information about participants that is important to their health and wellbeing. In many cases, the information is not anticipated in advance, and participants did not consent to receiving it. This Article examines the law and policy governing human subjects research, focusing on the set of regulations known as the “Common Rule.” I argue that human subjects researchers will often have strong ethical reasons to disclose results even when participants did not consent to the disclosure in advance. I also show how the current regulatory scheme stands in the way of ethical disclosures, putting researchers in a difficult position where they might not be able to fulfill their ethical duties without transgressing legal ones. Although we need to contend with autonomy and welfare risks associated with returning results, not to mention financial and administrative costs, these downsides are similarly present in analogous scenarios where non-consensual warnings are legally permitted and sometimes even required. There does not appear to be any good reason to make a policy exception for biomedical researchers when it comes to issuing warnings in the form of information disclosure. To aid difficult determinations about which results warrant return, I suggest that policymakers should take advantage of the interest and willingness of the bioethics community to develop consensus norms and incorporate these norms into regulations such that the

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regulations would at least permit researchers to disclose results whenever consensus standards would recommend disclosure. In this way, the law would make space for ethically optimal conduct without necessarily compelling it. At the same time, bioethicists and researchers should train their attention on non-ideal consent settings – the focus of this Article – rather than continuing to assume or hope that participants will have a chance to consent to the disclosure of results in advance.

CONTENTS

| | |
|--|-----|
| INTRODUCTION | 220 |
| I. HEALTH-RELEVANT RESULTS AND THEIR VALUE | 227 |
| A. What is a Health-Relevant Result?..... | 228 |
| B. The Value of Health-Relevant Results | 232 |
| II. CONSENT AND THE RETURN OF RESULTS | 233 |
| A. The Literature | 234 |
| 1. Consent to research..... | 237 |
| 2. Consent to the return of results | 241 |
| B. The Legal Landscape..... | 244 |
| 1. The Common Rule | 244 |
| 2. Other rules..... | 253 |
| C. The Practice | 254 |
| III. THE REASON TO RETURN RESULTS..... | 257 |
| A. The Ethics of Informing..... | 258 |
| B. The Law of Informing | 264 |
| C. A Right Not to Know? | 269 |
| D. Non-Consensual Research | 272 |
| E. Expectations..... | 277 |
| F. Costs to Researchers | 278 |
| G. Regulatory Reform..... | 280 |
| CONCLUSION | 283 |

INTRODUCTION

In the course of biomedical research on humans – for example, flu, imaging, and genomic studies – researchers often uncover information about participants that is important to their health and wellbeing and sometimes even the wellbeing of others. In many

cases, the information is not anticipated in advance, and participants did not consent to receiving it.

When the first U.S. COVID-19 case appeared in Washington state in late January of 2020, a group of researchers had already been collecting nasal swab samples from Seattle-area residents for months as part of the Seattle Flu Study, and they had thousands of recent samples in their possession.¹ Naturally, the researchers wondered if they could learn something about COVID-19 and its prevalence in the area by testing their samples for the virus. But the researchers did not anticipate, at the time of collection, that they would have reason to test their samples for the novel coronavirus. Although their participants had consented to influenza testing – the focus of the study – they had not consented to having their samples tested for the coronavirus, nor to the disclosure of results from any such testing, whether to themselves or public health authorities.² Moreover, the research team’s COVID-19 test had not been approved by the Food and Drug Administration (FDA), and their laboratory was not certified as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA), a federal regulation that requires labs conducting diagnostic testing to acquire special certification.³

Aware of potential legal and ethical issues, the research team attempted to get approval from federal and state officials to test their samples for COVID-19, but officials declined to approve the plan.⁴ The researchers believed that they had an ethical duty to test their samples for the virus, and the Study’s Institutional Review Board

1. Helen Y. Chu, Janet A. Englund, Lea M. Starita, Michael Famulare, Elisabeth Brandstetter, Deborah A. Nickerson, Mark J. Rieder, Amanda Adler, Kirsten Lacombe, Ashley E. Kim, Chelsey Graham, Jennifer Logue, Caitlin R. Wolf, Jessica Heimonen, Denise J. McCulloch, Peter D. Han, Thomas R. Sibley, Jover Lee, Misja Ilcisin, Kairsten Fay, Roy Burstein, Beth Martin, Christina M. Lockwood, Matthew Thompson, Barry Lutz, Michael Jackson, James P. Hughes, Michael Boeckh, Jay Shendure & Trevor Bedford, *Early Detection of Covid-19 Through a Citywide Pandemic Surveillance Platform*, 383 *NEW ENG. J. MED.* 185, 186 (2020); Gregory Conko, *Regulation, Confusion, and the Irony of Emergency COVID-19 Testing*, *COMPETITIVE ENTER. INST.* (Mar. 16, 2020), <https://cei.org/blog/regulation-confusion-and-irony-emergency-covid-19-testing>.

2. Chu et al., *supra* note 1; Sheri Fink & Mike Baker, *‘It’s Just Everywhere Already’: How Delays in Testing Set Back the U.S. Coronavirus Response*, *N.Y. TIMES* (Mar. 10, 2020), <https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html>.

3. See Fink & Baker, *supra* note 2. For more on CLIA, see *infra* Section II.B.2.

4. See Fink & Baker, *supra* note 2; Michael Barbaro, *Why the U.S. Wasn’t Ready for the Coronavirus*, *N.Y. TIMES: THE DAILY* (Mar. 11, 2020), <https://www.nytimes.com/2020/03/11/podcasts/the-daily/coronavirus-us-testing.html>.

(IRB) agreed with that assessment. The researchers accordingly proceeded with testing, despite the lack of agency permission.⁵ Many samples tested positive, and the team reported their findings to public health officials and at least some participants.⁶

Information provided on the Flu Study's website, however, indicated that "[p]articipants who signed a consent form after March 4 are eligible to receive COVID-19 results[.]" implying that participants who did not sign a consent form after March 4 would not receive such results.⁷ Presumably, this is because after March 4 the research team implemented revised consent materials that included information about COVID testing. And, indeed, regulators had apparently informed the researchers that they could test for the virus and report results, but only for participants who had consented to it.⁸

Regardless of the ethics of the researchers' decision to test existing samples for COVID-19 and share results, multiple regulatory obstacles stood in their way. This Article focuses on key regulatory provisions concerning informed consent and the disclosure of individual results. The portion of the federal regulations governing human subjects research known as the "Common Rule" requires researchers to inform study participants, at the consent stage, whether individual findings will be returned to them.⁹ Although the Seattle Flu Study's original consent

5. Fink & Baker, *supra* note 2.

6. Chu et al., *supra* note 1; Fink & Baker, *supra* note 2; Conko, *supra* note 1.

7. Leadership Update from the Seattle Flu Study, SEATTLE FLU STUDY, <https://wayback.archive-it.org/org-729/20200511225820/https://seattleflue.org/scan> (last visited Oct. 2, 2021).

8. Fink & Baker, *supra* note 2 (reporting that "federal and state officials said the flu study could not be repurposed because it did not have explicit permission from research subjects[.]" and that officials later relented in part, allowing the researchers "to test cases and report the results only in future samples[.]" provided that "they . . . use[d] a new consent form that explicitly mentioned that results of the coronavirus tests might be shared").

9. 45 C.F.R. § 46.116(c)(8) (2020). The "Common Rule" refers specifically to Subpart A of 45 C.F.R. § 46. Kayte Spector-Bagdady, *Governing Secondary Research Use of Health Data and Specimens: The Inequitable Distribution of Regulatory Burden Between Federally Funded and Industry Research*, 8 J. OF L. AND BIOSCIENCES 1, 9 (2021). The remaining Subparts (B–D) provide "additional protections for vulnerable populations, such as children." *Id.* The Common Rule generally applies to federally funded research involving human subjects. 45 C.F.R. § 46.101. Many research entities, however, adopt Common Rule requirements for all human subjects research, regardless of funding source. *Protecting Research Volunteers: Is All Human Subjects Research Regulated*, OFF. FOR HUM. RSCH. PROT., <https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/protecting-research-volunteers/>

materials likely included provisions about the return of regular flu test results, those materials naturally did not inform participants that novel coronavirus results might be returned to them or public health authorities. Arguably, then, the consent materials did not support the return of those results to anyone, and the researchers violated the Common Rule when they disclosed them.

Legal issues aside, the Seattle Flu Study case would seem to be an easy one in terms of ethics. Once it became apparent that the virus was spreading in the United States, the flu researchers were ethically permitted, and possibly even required, to test their samples for COVID-19 and report the results. This testing and reporting could serve to mitigate a public health crisis, because information about infected individuals could help public health officials as well as affected individuals themselves track their contacts and limit further transmission. As the Study's research team explains, "[t]he first COVID-19 case detected through the Seattle Flu Study . . . was the first documented U.S. case of community transmission at the time"; the Study's COVID-19 testing "initiated assessment of the spread of the virus in the Seattle region, which in turn accelerated public health efforts to mitigate the emerging pandemic."¹⁰

Individuals who received positive test results could also act on the information in ways that would benefit them—by taking measures to protect their loved ones and community members from infection, for example, and by preparing for possible medical interventions, including hospitalization. The advantages of testing samples for COVID-19 and reporting results were exacerbated by the fact that the United States had been notoriously lethargic in its testing efforts. Given the limited availability of testing, especially in

other-research/index.html (last reviewed Jan. 28, 2020) (stating that, "many institutions voluntarily apply the protections laid out in the Common Rule"). See, e.g., *The Common Rule*, U.C. DAVIS OFFICE OF RSCH., <https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/federal-funding/> (last visited Oct. 15, 2021) (requiring that all studies, regardless of funding source, comply with certain Common Rule requirements); *Institutional Review Board Human Research Protections: 2018 Common Rule Frequently Asked Questions (FAQs)*, UCI OFF. OF RSCH. 1, 2 (Jan. 25, 2019), <https://webcache.googleusercontent.com/search?q=cache:ZCY2rV7AFfkJ:https://research.uci.edu/compliance/human-research-protections/researchers/2018-common-rule-faqs.pdf+&cd=19&hl=en&ct=clnk&gl=us&client=firefox-b-1-d> (requiring that "[a]ll studies approved by the IRB on or after January 21, 2019 must transition [to new regulatory requirements] regardless of funding.").

10. Chu et al., *supra* note 1.

the early weeks of the pandemic in the United States, many individuals were effectively denied access to COVID tests.¹¹

The downsides of running COVID-19 tests on samples that were originally collected for different purposes pale in comparison to the benefits. Perhaps some individuals would rather *not* know that they had or have the coronavirus—for example, because they might be ordered to quarantine, depending on when the sample was collected, or because of stigma associated with testing positive. Another risk of informing participants of the results of a test to which they did not consent is the possibility of damaging public trust in biomedical research and perhaps even the health care system. Given the major advantages to testing existing Flu Study samples for COVID-19 and reporting the results, though, the researchers' decision to do so would seem to be ethically sound.

One might accept this ethical evaluation of the Flu Study team's decision to test their samples for COVID-19 and report results, and still insist that a general rule against disclosing medical results without advanced consent is appropriate. One might think that the pandemic posed an anomalous exception to the rule. This Article argues, to the contrary, that human subjects researchers will often have strong ethical reasons to disclose results to participants even when those participants did not consent to the disclosure in advance, and not only in the context of a public-health emergency.

11. Michael D. Shear, Abby Goodnough, Sheila Kaplan, Sheri Fink, Katie Thomas & Noah Weiland, *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, N.Y. TIMES (Mar. 28, 2020), <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html> (reporting that, as COVID-19 spread “across the United States between late January and early March, large-scale testing of people who might have been infected did not happen—because of technical flaws, regulatory hurdles, business-as-usual bureaucracies and lack of leadership at multiple levels,” and that even in late March, many U.S. residents did not have access to testing and “hospitals and clinics across the country [had to] deny tests to those with milder symptoms, trying to save them for the most serious cases, and they often wait a week for results”); Denise M. Dudzinski, Benjamin Y. Hoisington & Crystal E. Brown, *Ethics Lessons from Seattle's Early Experience with COVID-19*, 20 AM. J. BIOETHICS 67, 69 (2020) (“Flaws in the [CDC] testing kits, unnecessary delays in the [FDA's] approval of [the University of Washington's] test, and insufficient national testing capability created a perfect storm when [COVID-19] landed in Seattle.”); Andrew Hay, *Washington State Urges Patience as Covid-19 Test Delays Stoke Anger*, REUTERS (Mar. 4, 2020), <https://www.reuters.com/article/us-health-coronavirus-usa-tests/washington-state-urges-patience-as-covid-19-test-delays-stoke-anger-idUSKBN20S096> (“Washington state officials urged patience [in early March] as medical staff reported fear and anger among people told they could not be tested for the coronavirus due to limited capacity in a state facing the United States' deadliest outbreak.”).

The current regulatory scheme, however, imposes obstacles to ethical disclosures. To this extent, the law conflicts with bioethics, putting researchers in a difficult position, where they might not be able to fulfill their ethical duties without transgressing legal ones.

A large body of bioethics literature, developed mainly over the past twenty years, focuses on whether and under what circumstances research participants have a right to receive individual results. Bioethicists widely agree that researchers should address the question of returning individual results at the consent stage. And their conclusions generally rest on the premise that researchers have done so. According to the consensus view, researchers should return individual results under certain conditions, provided that participants consented to the return of results in advance of the study.¹²

But the literature has largely evaded the more difficult questions of whether and under what conditions researchers should return results even if participants have *not* consented to the disclosure—which can happen if the consent form indicated that results would not be disclosed, the form was silent or ambiguous on the matter, or participants did not consent to participate in the research at all. Although I agree with the consensus view that ideally consenting participants would be informed upfront that certain findings will be disclosed to them, the reality is that, for various reasons—some of them morally acceptable and others not—participants often are not so informed.¹³ The Seattle Flu Study, where participants were recruited for one purpose but then their biospecimens were used for another, is just one example. And so we need to grapple with the question of the disclosure of individual results in non-ideal consent settings. This is a matter of pressing, and increasing, importance, as biomedical studies with human participants, on which the health and wellbeing of society depend, proliferate. We have to ask not only what these participants can do for research, but what research can do for them, especially when the research might infringe on their rights and threaten their interests.

Researchers often uncover individual, health-relevant findings—for example, a genetic abnormality that indicates an increased probability of developing a life-threatening disease—in

12. For a discussion of this literature, see *infra* Section II.A.

13. See *infra* Section II.C.

the course of their studies. Currently, the regulations impose no requirements on researchers to share such results, and actually create obstacles to disclosure in various scenarios, thus making it less likely that researchers will disclose individual findings. Other legal provisions create further obstacles to that effect.

Although the context of a public health emergency made the return of results in the Seattle Flu Study case particularly important and urgent, even in the absence of any public health crisis researchers will often have strong ethical reasons to return individual results that are relevant to participants' health and the health of others—even if participants did not give their informed consent to the disclosure in advance. To support this claim, I develop analogies to other situations where experts have special access to information that is relevant to the health and wellbeing of others and where it is more widely accepted and apparently intuitive that the experts have moral reasons, and in some cases even legal ones, to share the information with those likely to be affected by it. There is no good reason to make an exception for human subjects researchers when it comes to the disclosure of information. To the extent that the law reflects such an exception, it promotes ethically problematic conduct and undermines the rights and interests of research participants.

I argue further that the ethical reasons in favor of returning results can be even stronger in the context of non-consensual, as opposed to consensual, research. This is because researchers infringe on the rights of those whom they engage in research without consent, and they therefore owe non-consensual participants greater care and compensation in return. My analysis shows that prevailing theories about the ethics of returning results, which ground any duties to disclose in the consent process, are at best incomplete and at worst entirely misdirected. I focus on genomic research on humans, since this is a common setting for the discovery of individual, health-relevant findings, but my conclusions extend to other types of biomedical research as well, including flu studies and imaging studies.

For the good of both society and participants to research, the law should, at the least, permit investigators to return certain individual findings to those affected by them—certainly in public health emergencies such as the outbreak of COVID-19 in the United States, but also under normal circumstances. The COVID-19

example shows how high and urgent the stakes can be but should not be seen or treated as an exception to a rule against returning individual results. Bioethicists, biomedical researchers, legal scholars, and other experts and stakeholders should turn their attention to non-ideal consent settings and develop consensus norms regarding which types of finding warrant return in these settings. This Article lays the groundwork for that project. I suggest that policymakers should take advantage of the willingness and interest on the part of the bioethics community to develop and disseminate consensus norms, through the regulatory incorporation of the standards that develop, at least to the extent of permitting the return of results whenever the consensus view recommends disclosure. Researchers should at least be legally permitted to disclose results when that disclosure is ethically advisable.

The Article proceeds as follows. In Part I, I describe the concept of health-relevant individual results and explain their informational value. In Part II, I show how existing arguments in favor of duties to return individual results in human subjects research generally presuppose an ideal consent backdrop and thus evade the critical question of how researchers should handle individual results in non-ideal consent settings. I show further how the statutes and regulations governing human subjects research invite investigators to refrain from disclosing results and even create barriers to doing so. In Part III, I argue that the return of results, under certain conditions, is morally desirable and that this is the case even, and indeed sometimes especially, if participants did not consent to disclosure in advance. I show moreover how judicial decisions have absorbed ethical principles and intuitions and recognized duties to warn in analogous contexts. And finally, I propose a path for regulatory reform that would take advantage of consensus standards developed by bioethicists and other relevant professionals, and that would recognize the rights and interests of participants who contribute to research under non-ideal consent conditions.

I. HEALTH-RELEVANT RESULTS AND THEIR VALUE

I will argue that the law generally should not prevent or discourage researchers from disclosing individual health-relevant results to their participants. In this Part, I offer a rough definition of health-relevant results, recognizing that the bioethics community will need to work out further details.

A. What is a Health-Relevant Result?

An individual health-relevant result is a finding about a particular participant that researchers uncover in the course of research and that is significant to the health or wellbeing of the participant.¹⁴ Individual results are only health relevant if they are reasonably trustworthy or “analytically valid.”¹⁵ Of course, findings are never one hundred percent reliable. They are subject to multiple types of error, including basic human errors in reading and recording. As long as a result conveys substantially more signal than noise, though, it can help inform an individual’s health-related decisions. Moreover, the level of analytic validity required to make an individual result health relevant depends on the extent to which individuals have reasonable access to further testing that would yield more certain results.¹⁶

The likelihood that human subjects researchers will discover health-relevant individual findings depends on the nature of the research. For example, in the case of the Seattle Flu Study, the researchers would be unlikely to discover any findings aside from the flu test results and then the COVID-19 results once they subjected the samples to COVID testing. Many studies are highly targeted and the set of individual results that might be uncovered is narrow. Other studies, however—for example, some imaging studies and genetic sequencing studies—have the potential to uncover a wide range of health-relevant results about participants.¹⁷ As Ben Chan

14. Sharon Terry highlights the tension between “usefulness from the participant perspective” and “clinical utility,” and discusses possibilities for managing this tension in the context of decision making about what kinds of result warrant return. 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, 709–11 (2012).

15. See Richard R. Fabsitz, Amy McGuire, Richard R. Sharp, Mona Puggal, Laura M. Beskow, Leslie G. Biesecker, Ebony Bookman, Wylie Burke, Esteban Gonzalez Burchard, George Church, Ellen Wright Clayton, John H. Eckfeldt, Conrad V. Fernandez, Rebecca Fisher, Stephanie M. Fullerton, Stacey Gabriel, Francine Gachupin, Cynthia James, Gail P. Jarvik, Rick Kittles, Jennifer R. Leib, Christopher O’Donnell, P. Pearl O’Rourke, Laura Lyman Rodriguez, Sheri D. Schully, Alan R. Shuldiner, Rebecca K.F. Sze, Joseph V. Thakuria, Susan M. Wolf & Gregory L. Burke, *Ethical and Practical Guidelines for Reporting Research Results to Study Participants: Updated Guidelines from a National Heart, Lung, and Blood Institute Working Group*, 3 CIRCULATION & CARDIOVASCULAR GENETICS 574, 575 (2010) (suggesting that individual results must be analytically valid to warrant return).

16. See *infra* note 30 on related justice concerns.

17. For example, neuroimaging studies uncover incidental findings “in up to forty-seven percent of supposedly normal adult control research participants,” and “colonography

and coauthors observe, when researchers use whole exome- or genome-sequencing technologies, they will “nearly inevitabl[y] uncover] . . . some actionable variations . . . for every research participant.”¹⁸ This is because such sequencing typically turns up tens of thousands of genetic variants for each participant, some of which will be “associated with a significant increase in risk of disease for the proband [participant or donor] and [their] relatives.”¹⁹ As genetics and medicine advance, opportunities for researchers to uncover information about the health of participants are continually increasing.²⁰

Bioethicists often distinguish among “primary,” “secondary,” and “incidental” or “collateral” findings.²¹ Primary findings are results that the researchers are looking for directly and that are generated to answer the main research questions; secondary findings are also directly sought, but they do not answer the main research questions; and incidental findings are results that are uncovered unintentionally in the course of research. For an example of the latter, a study of heart function might involve imaging of the torso region that reveals abnormalities, such as tumors, in organs that are not directly under study.²² On my

reveals extracolonic findings in about half of scans in asymptomatic participant populations.” Susan M. Wolf, Jordan Paradise & Charlisse Caga-anan, *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers’ Duties*, 36 J.L. MED. & ETHICS 361, 362 (2008) [hereinafter *Law of Incidental Findings*].

18. Ben Chan, Flavia M. Facio, Haley Eidem, Sara Chandros Hull, Leslie G. Biesecker & Benjamin E. Berkman, *Genomic Inheritances: Disclosing Individual Research Results from Whole-Exome Sequencing to Deceased Participants’ Relatives*, 12 AM. J. BIOETHICS 1, 2 (2012).

19. *Id.*

20. See, e.g., Valerie Gutmann Koch, *A Private Right of Action for Informed Consent in Research*, 45 SETON HALL L. REV. 173, 175 (2015) (“[W]ith almost daily genetic and medical discoveries, there is an ever-increasing possibility of finding out information about the research participant that is beyond the scope of the protocol.”).

21. See, e.g., Stephanie R. Morain, Kevin Weinfurt, Juli Bollinger, Gail Geller, Debra JH Mathews & Jeremy Sugarman, *Ethics and Collateral Findings in Pragmatic Clinical Trials*, 20 AM. J. BIOETHICS. 6 (2020) (presenting a framework for analyzing whether researchers have a duty to return individual collateral findings in the context of pragmatic clinical trials).

22. As Susan M. Wolf, Frances P. Lawrenz, Charles A. Nelson, Jeffrey P. Kahn, Mildred K. Cho, Ellen Wright Clayton, Joel G. Fletcher, Michael K. Georgieff, Dale Hammerschmidt, Kathy Hudson, Judy Illes, Vivek Kapur, Moira A. Keane, Barbara A. Koenig, Bonnie S. LeRoy, Elizabeth G. McFarland, Jordan Paradise, Lisa S. Parker, Sharon F. Terry, Brian Van Ness & Benjamin S. Wilfond, *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 228 (2008) [hereinafter *Managing Incidental Findings*], explain, “The risk of [incidental findings] is intrinsic to research generating any information beyond the variables directly under study.”

analysis, however, whether the finding is primary, secondary, or incidental typically makes little difference to the ethics of returning it; accordingly, with some qualifications, I do not treat the different types of finding separately.

An individual research finding can be health relevant in at least two different ways. First, a result is health relevant if, based on that finding, the individual would know that they have a substantial chance of developing a serious disease.²³ The result would be more health relevant if it is actionable – that is, if the individual could take actions to mitigate or prevent the development of the disease.²⁴ For example, the discovery that an individual has one of the breast-cancer genes (BRCA1 or BRCA2) is health relevant in this way. A positive BRCA1 or BRCA2 test indicates a substantial chance of developing a life-threatening form of breast cancer.²⁵ Moreover, an individual can significantly reduce that risk by undergoing preventive surgery.²⁶ A finding might be health

23. Other commentators have similarly suggested that results must meet this kind of minimum requirement in order to warrant return. *See, e.g.,* Fabsitz et al., *supra* note 15, at 575 (reporting that their working group recommended that results be returned if (among other conditions) they have “important health implications . . . and the associated risks are established and substantial”); Stephanie A. Alessi, *The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?*, 64 HASTINGS L.J. 1697, 1722 (2013) (arguing that “researchers should have a legal duty to offer to disclose certain results that present a serious and foreseeable harm”). Scholars have been reluctant to quantify the appropriate risk threshold. Perhaps the appropriate threshold should depend on the severity of the disease at issue.

24. As others have noted, “the evidence base for ‘actionability’ of results will change [most likely grow] over time and the number of such results will also increase” Yvonne Bombard, Kenneth Offit & Mark E. Robson, *Risks to Relatives in Genomic Research: A Duty to Warn?*, 12 AM. J. BIOETHICS 12, 13 (2012).

25. *See, e.g.,* Karoline B. Kuchenbaecker, John L. Hopper, Daniel R. Barnes, Kelly-Anne Phillips, Thea M. Mooij, Marie-José Roos-Blom, Sarah Jervis, Flora E. van Leeuwen, Roger L. Milne, Nadine Andrieu, David E. Goldgar, Mary Beth Terry, Matti A. Rookus, Douglas F. Easton, Antonis C. Antoniou & the BRCA1 and BRCA2 Cohort Consortium, *Risks of Breast, Ovarian, and Contralateral Breast Cancer for BRCA1 and BRCA2 Mutation Carriers*, 317 JAMA 2402, 2410, 2412 (2017) (finding, based on a study of BRCA1 and BRCA2 carriers, that “the cumulative risk of developing breast cancer by age 80 years was 72% for BRCA1 mutation carriers and 69% for BRCA2 mutation carriers, respectively,” but noting that, since the study participants “included women who, on average, are likely to have stronger family history of cancer compared with mutation carriers identified through population-based sampling,” the risks for carriers who do not have a family history of cancer might be lower).

26. *What To Do If You’ve Tested Positive*, NAT’L BREAST CANCER FOUND., INC., <https://www.nationalbreastcancer.org/what-to-do-if-youve-tested-positive> (last visited Sept. 28, 2021) (explaining that preventive surgeries decrease the risk of breast cancer by ninety percent); *Medical Options for Women with BRCA1 and BRCA2 Mutations*, CTRS. DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/genomics/disease/breast_ovarian_

relevant, however, even if the affected individual could not take any measures to reduce the risk or severity of the disease.²⁷ This is because the result could provide information about one's future health that might affect one's life decisions. For example, one might decide to change certain life plans, both major—such as what kind of family to have—and minor—such as when to travel or pursue certain activities.

Second, a result is health relevant if it is likely to affect an individual's reproductive decisions. For example, if someone learns that they are a carrier of the gene for cystic fibrosis (a recessive disorder), that knowledge might inform decisions around reproduction, such as whether their partner should be tested for the CF gene and whether they will have a diagnostic fetal test for CF during pregnancy. If both parents are carriers, then there is a twenty-five percent chance that their child will develop cystic fibrosis and a fifty percent chance that their child will be a carrier.²⁸ Positive results for other genetic variations, such as the gene for Huntington's disease (a late-onset, dominant disorder, with high-penetrance) might likewise affect reproductive decisions.²⁹

One could disagree to some extent with my conception of a health-relevant result and still accept my broader argument about the return of results. One might agree that, under certain

cancer/medical_options.htm (asserting that mastectomy is the most effective form of cancer prevention) (last visited Sept. 28, 2021).

27. Others have argued that individual results should not be returned unless the result is "actionable" in the sense that "there are established therapeutic or preventive interventions . . . that have the potential to change the clinical course of the disease." Fabsitz et al., *supra* note 15, at 575. I disagree with this limitation because individuals might make meaningful decisions in light of certain results, which create value in their lives, even if those decisions do not involve medical interventions. An example of a result that is *not* health relevant on my view is evidence of mild cognitive impairment (MCI): as Lisa Parker explains, "[T]he clinical utility of a MCI diagnosis has not been established. . . . its diagnostic criteria are not consistently utilized, and relevant clinical communities cannot agree on the meaningfulness of a finding of MCI." Lisa S. Parker, *The Future of Incidental Findings: Should They Be Viewed as Benefits?*, 36 J.L. MED. & ETHICS 341, 348 (2008).

28. *Carrier Testing for Cystic Fibrosis*, CYSTIC FIBROSIS FOUND., <https://www.cff.org/What-is-CF/Testing/Carrier-Testing-for-Cystic-Fibrosis/> (last visited Sept. 28, 2021).

29. If an individual tests positive for the Huntington's gene, then it is almost certain that they will develop the disease. See *The Genetics of Huntington's Disease*, HUNTINGTON'S DISEASE ASS'N, <https://www.hda.org.uk/huntingtons-disease/what-is-huntingtons-disease/genetics-of-huntingtons-disease> (last visited Sept. 28, 2021). If one parent has the gene a child has a fifty-percent chance of inheriting it, and if both parents have the gene a child has a seventy-five percent chance of inheriting it. *Id.*

circumstances, it is appropriate for researchers to return individual results to participants, while believing that the universe of health-relevant results is bigger or smaller or just different than the universe that I envision. In any event, it is undeniable that researchers uncover some individual results in the course of research with human subjects that are significantly relevant to participant wellbeing. This Article argues that, on moral grounds, returning such results will often be praiseworthy if not obligatory, and that law and policy are therefore defective insofar as they stand in the way of disclosure.

B. The Value of Health-Relevant Results

As various commentators have suggested, individual results that researchers uncover—whether primary, secondary, or incidental—can be highly valuable to participants for a variety of reasons. Disclosing results supports individual autonomy because it gives individuals the opportunity to make informed decisions about their healthcare and to plan for the future.³⁰ An individual's autonomy might be substantially curtailed if they are blindsided by the effects of a disease, whether in themselves or their children. And receiving forewarning in the form of individual results from a research study can help to prevent that eventuality. Armed with the information that researchers provide by returning findings, individuals might be able to take actions to mitigate or even prevent disease, or at least to plan ahead for the eventuality of developing a disease.³¹

30. Individuals without access to healthcare, however, will have more limited options. They may not be able to obtain further testing, preventive care, or treatment. People will also have different capacities to process and comprehend the information disclosed to them, disparities which have to be taken into account when considering the best disclosure processes to adopt. *See, e.g., Terry, supra note 14*, at 721 (asserting that people “with different levels of literacy will require different levels of support, which will require varying methods of education and a sundry of follow-up activities”). These represent critical distributive justice issues which have to be worked out, but which I set aside for now.

31. Various diseases are fatal if diagnosed late but can be cured if diagnosed early or prevented if the risk of disease is identified before symptoms materialize. An example is medullary thyroid carcinoma (MTC), which is associated with a genetic abnormality in twenty-five percent of cases. *See Medullary Thyroid Cancer*, AM. THYROID ASS'N, <https://www.thyroid.org/medullary-thyroid-cancer/> (last visited Oct. 15, 2021). The prognosis of MTC is highly dependent on how early it is diagnosed; it can be cured with surgery if diagnosed early, but the prognosis is poor if diagnosed late. *Id.* Another example is long QT syndrome, which causes sudden cardiac death, but can be treated to decrease the

Some of the options available to an individual who discovers their risk factor before symptoms develop will be foreclosed once the disease materializes. And, assuming that people will act in their own best interests, disclosing results promotes not only autonomy but also well-being. A multidisciplinary group of twelve scholars has argued in favor of a duty to return findings “based on researcher obligations to respect subjects’ autonomy and interests”³²

Of course, there are also non-trivial risks associated with learning information about one’s current or future health. The result might contribute to anxiety and depression. The result might be misleading, and the recipient might unnecessarily change life plans in response to it. As I argue below, however, the risks associated with information disclosure in this context are not unique and do not justify special prohibitions or restrictions on returning individual research results.³³

The question of exactly which results should be returned is beyond the scope of this Article. As I suggest below, the bioethics community should work to develop guidance, on which policymakers and enforcers can rely, concerning which results qualify as “health-relevant” such that they warrant disclosure even if consent for the disclosure was not initially obtained.³⁴

II. CONSENT AND THE RETURN OF RESULTS

In this Part, I review the literature, the law and policy, and the practice of the return of individual, health-relevant results to research participants. First, I draw attention to the prevalence of published guidance from bioethicists and researchers on the topic

risk of cardiac death if detected in time. Anneke Lucassen & Michael Parker, *Confidentiality and Sharing Genetic Information with Relatives*, 375 LANCET 1507, 1508 (2010). As D’ Auffriet Van Haecke and de Montgolfier explain, “[t]he utility of knowing” that one has an increased risk for a certain disease—for example, types of cancer and metabolic illnesses—is that “there are screening options or preventive therapies that can forestall the onset of the disorder or improve individual prognosis, and in some cases even prevent death.” Diane d’ Audiffret Van Haecke & Sandrine de Montgolfier, *Genetic Test Results and Disclosure to Family Members: Qualitative Interviews of Healthcare Professionals’ Perceptions of Ethical and Professional Issues in France*, 25 J. GENETIC COUNSELING 483, 483 (2016).

32. Judy Illes, Matthew P. Kirschen, Emmeline Edwards, L.R. Stanford, Peter Bandettini, Mildred K. Cho, Paul J. Ford, Gary H. Glover, Jennifer Kulynych, Ruth Macklin, Daniel B. Michael, Susan M. Wolf & members of the Working Group on Incidental Findings in Brain Imaging Research, *Incidental Findings in Brain Imaging Research*, 311 SCI. 783, 783 (2006).

33. See *infra* Part III.

34. See *infra* Section III.G.

of the return of results, and in particular efforts to develop and disseminate consensus norms or standards, and I point out a fundamental limitation with this literature – existing theories about the ethics of returning results ground reasons to return in participants’ voluntary consent to research and thus neglect the rights and interests of non-consensual research participants. Second, I explain how the law governing human subjects research creates incentives for researchers to refrain from obtaining consent to the return of results in advance and in turn to refrain from returning results. And third, I observe that researchers often choose not to return results despite empirical evidence suggesting that participants wish to receive them.

A. The Literature

Bioethicists and human subjects researchers have produced a wealth of literature on consent and the return of results, often as part of large, multi-disciplinary collaborations. They generally argue that, in the context of consensual human subjects research, researchers have some, although limited, ethical duties to return individual health-relevant results, and that researchers should inform participants about the return of results as part of the informed consent process. This is perhaps the prevailing or consensus view.³⁵ According to Rebecca Branum and Susan Wolf, “there is wide agreement that investigators have a responsibility to anticipate discovery of findings that may warrant return, to incorporate in protocols a plan for evaluating such findings, and to offer at least some of these results to participants consenting to

35. See, e.g., Matthew P. Gordon, *A Legal Duty to Disclose Individual Research Findings to Research Subjects?*, 64 *FOOD & DRUG L.J.* 225, 235 (2009) (“[I]n situations where the research finding would have significant clinical utility to the subject, there appears to be broad agreement, based in large part on the principle of respect for persons, that there is a moral obligation to disclose.”); William McGeeveran, Leili Fatehi & Pari McGarraugh, *Deidentification and Reidentification in Returning Individual Findings from Biobank and Secondary Research: Regulatory Challenges and Models for Management*, 13 *MINN. J.L. SCI. & TECH.* 485, 524 (2012) (recognizing “a growing belief that researchers should return individual findings in at least some situations”); Emily Scholtes, *Incorporating Cost into the Return of Incidental Findings Calculus: Defining a Responsible Default for Genetics and Genomics Researchers*, 100 *MINN. L. REV.* 1171, 1192 (2016) (“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.”).

such return.”³⁶ Scholars ground duties to return results to participants in principles of gratitude, reciprocity, and autonomy.³⁷

A minority of commentators, however, insists that researchers do not have any obligation to return individual results, since the return of results amounts to a kind of clinical care, which is beyond the scope of the researcher-participant relationship.³⁸ Moreover, it will often be costly and impracticable for researchers to recontact participants when important health-related findings are discovered.³⁹

Despite some differences in opinion about whether researchers have ethical duties to return results, commentators widely agree that researchers should inform participants, through the consent process, about the possibility of uncovering individual results and whether or not such results will be returned to participants.⁴⁰ Those in favor

36. Rebecca Branum & Susan M. Wolf, *International Policies on Sharing Genomic Research Results with Relatives: Approaches to Balancing Privacy with Access*, 43 J.L. MED. & ETHICS 576, 576 (2015).

37. For arguments that explain duties to return in these terms, see *infra* Section II.A.1.

38. See, e.g., Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomic Research*, 14 GENETIC MED. 473, 475 (2012) (“If there is some sort of notification or consent, it may state explicitly that individual results will not be returned due in part to the difficulties return presents.”); 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, 443–44 (2012) (explaining that, “[t]he researcher has been seen as owing limited duties to the individual research participants, in contrast to the clinician, who undertakes a broad duty of care towards the individual patient” and that, “the return of results debate . . . forces us to rethink the traditional wall between research and clinical care . . .”); Terry, *supra* note 14, at 719 (“Researchers, while in a gray area of interaction with participants, unlike clinicians, do not take a Hippocratic Oath and have no formal clinical professional codes of conduct.”).

39. See, e.g., Clayton & McGuire, *supra* note 38, at 476 (while there may be exceptional “cases in which disclosure of research results should be encouraged, . . . [g]reat caution should be taken to ensure that these exceptions are not generalized to create a rule requiring disclosure, especially for results generated distant in place and particularly in time from data collection.”).

40. See, e.g., Gail E. Henderson, Susan M. Wolf, Kristine J. Kuczynski, Steven Joffe, Richard R. Sharp, D. Williams Parsons, Bartha M. Knoppers, Joon-Ho Yu & Paul S. Appelbaum, *The Challenge of Informed Consent and Return of Results in Translational Genomics: Empirical Analysis and Recommendations*, 42 J.L. MED. & ETHICS 344, 354 (2014) (proposing a list of information about the return of results that participants should receive during the consent process, including a description of “possible results related to diagnostic or incidental findings” that might be uncovered, as well as a statement of “the likelihood of producing such results” and “whether they are related to conditions that are preventable [or] treatable . . .”); Bartha Maria Knoppers, Yann Joly, Jacques Simard & Francine Durocher, *The Emergence of an Ethical Duty to Disclose Genetic Research Results: International Perspectives*, 14 EUR. J. HUM. GENETIC 1170, 1176 (2006) (asserting that “the

of the return of results insist that the return of results “should be offered as part of the original consent process and re-offered at the conclusion of the study.”⁴¹ The Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans provides that “researchers shall inform participants, as part of the initial consent process, of the likelihood of discovering material incidental findings, and where applicable, should provide information on their strategy to disclose such findings to participants.”⁴² On the other side are those who deny that

issue of notifying (or not) participants of results should be disclosed and agreed to in advance (ie [sic] on the consent form”).

41. Conrad V. Fernandez, Eric Kodish & Charles Weijer, *Informing Study Participants of Research Results: An Ethical Imperative*, 25 IRB: ETHICS & HUM. RSCH. 12, 15 (2003); see also *Managing Incidental Findings*, supra note 22, at 238, 227 (arguing that researchers should offer to return results of “Strong Net Benefit” to participants and should “address the possibility of discovering [such findings] in their consent forms and communications with . . . participants.”); Timothy Caulfield, Amy L. McGuire, Mildred Cho, Janet A. Buchanan, Michael M. Burgess, Ursula Danilczyk, Christina M. Diaz, Kelly Fryer-Edwards, Shane K. Green, Marc A. Hodosh, Eric T. Juengst, Jane Kaye, Laurence Kedes, Bartha Maria Knoppers, Trudo Lemmens, Eric M. Meslin, Juli Murphy, Robert L. Nussbaum, Margaret Otlowski, Daryl Pullman, Peter N. Ray, Jeremy Sugarman & Michael Timmons, *Research Ethics Recommendations for Whole-Genome Research: Consensus Statement*, 6 PLOS BIOLOGY 430, 433 (2008) (arguing that researchers should inform participants, “in the initial consent [materials],” what types of individual results will be returned to them); Gaile Renegar, Christopher J. Webster, Steffen Stuerzebecher, Lea Hartly, Susan E. Ide, Beth Balkite, Taryn A. Rogalski-Slater, Nadine Cohen, Brian B. Spear, Diane M. Barnes & Celia Brazell, *Returning Genetic Research Results to Individuals: Points-to-Consider*, 20 BIOETHICS 24, 35 (2006) (arguing that researchers should ask participants whether they want to receive results at the enrollment stage and ask participants again before sharing findings).

42. CAN. INSTS. OF HEALTH RSCH., NAT. SCIS. AND ENG’G RSCH. COUNCIL OF CAN. & SOC. SCIS. AND HUMANS. RSCH. COUNCIL OF CAN., TRI-COUNCIL POLICY STATEMENT, ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS 34 (TCPS2 2018), <https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>; see also GENEVA: COUNCIL FOR INT’L ORGS. OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS 103 (4th ed. 2016) (providing that researchers must inform participants in the consent materials that they “will be informed of life-saving information and data of immediate clinical utility involving a significant health problem”); Comité de Ética del Instituto de Investigación de Enfermedades Raras (IIER), Inst. De Salud Carlos III. Madrid, Moisés Abascal Alonso, Francisco J. de Abajo Iglesias, Jaime Campos Castelló, Lydia Feito Grande, Joaquín Herrera Carranza, Javier Júdez Gutiérrez, M^a Concepción Martín Arribas, Amelia Martín Uranga, Teresa Pàmols Ros, M^a José Sánchez Martínez & Benedetto Terracini, *Recomendaciones Sobre Los Aspectos Éticos de Las Colecciones de Muestras y Bancos de Materiales Humanos con Fines de Investigación Biomédica*, 81 REV. ESP. SALUD PÚBLICA 95 (Feb. 27, 2007) (Spain) (advising that researchers should let participants choose, during the consent process, whether to be informed of individual results) noted in Ma’n H. Zawati, Brian Van Ness & Barbara Maria Knoppers, *Incidental Findings in Genomic Research: A Review of International Norms*, 9 GENEDIT 1, 4 (2011). Australian law even requires researchers to inform

researchers have ethical duties to return results; these commentators suggest that, if researchers prefer not to return results they should simply inform participants through the consent materials that results will not be returned.⁴³ Regardless of where commentators stand on researchers' duties to return individual results to participants, they widely agree that researchers ought to inform participants about the return of results upfront, at the informed consent stage of the research.

What if, for whatever reason, researchers did not obtain participant consent to the return of results in advance? If that is the case, might researchers nevertheless be permitted or even required to return results? To the limited extent that commentators have addressed this issue, they have generally suggested that researchers have no moral duty to return results if advanced consent to that return is lacking and that researchers might even be morally prohibited from returning results in this context.⁴⁴ I turn to these issues in the following two subsections.

1. *Consent to research*

It is the consensus view, then, that researchers have ethical duties to return results in the event that they obtained consent to the study and to the return of results upfront, during the consent process. But non-consensual research on human biospecimens and health data is prevalent. As Clayton reports, "a great deal of research is conducted without seeking individual consent, either because the IRB waives that requirement or because identifiers are removed so that the samples are no longer deemed to involve 'human subjects'"; "most people do not know how their DNA is

participants that results with important implications for the health of participants' relatives may be disclosed to those relatives. See Branum & Wolf, *supra* note 36, at 580.

43. Clayton & McGuire, *supra* note 38, at 475 (stating that researchers "may state explicitly" in the consent materials "that individual research results will not be returned due in part to the difficulties return presents").

44. For a notable exception, see generally Vardit Ravitsky & Benjamin S. Wilfond, *Disclosing Individual Genetic Results to Research Participants*, 6 AM. J. BIOETHICS 8 (2006) (suggesting that researchers should inform participants in advance that some results will be returned, but that even if they failed to do so, they should still return results with high clinical utility—even if the IRB waived the consent requirement on the condition that researchers would *not* share results with participants).

being used in research, what conditions are being investigated, or even that research is going on at all.”⁴⁵

In the United States, research might proceed without participants’ informed consent for a number of reasons. First, there are multiple legal paths available: researchers can obtain a waiver of the informed consent requirement from their IRB, or they can meet conditions for an exemption under the Common Rule.⁴⁶ And second, researchers might carry out studies with human subjects without obtaining informed consent even in cases where such consent is legally required, whether or not the violation is intentional.

The literature on researchers’ duties to return individual results often simply presupposes that the research is consensual and says little or nothing about duties to return results in non-consensual research. To the extent that recommendations do touch on such research, they tend to suggest, if only by implication, that researchers’ duties to return individual results are weaker or non-existent, or even that researchers have a duty *not* to return results, in this context. The National Heart, Lung, and Blood Institute Working Group (NHLBI Group), a multidisciplinary collaboration of twenty-eight experts, recommends that, in the event that researchers do not obtain informed consent to the study, no return of individual results is ethically required.⁴⁷ But the authors do not explain why researchers engaging in research without informed consent are absolved of a responsibility to return results. Other commentators, grounding duties to return results in the consent process or the participant’s voluntary participation, imply that researchers have an ethical reason to return results only in the case of consensual research. Franklin Miller, Michelle Mello, and Steven

45. Ellen Wright Clayton, *Incidental Findings in Genetics Research Using Archived DNA*, 36 J.L. MED. & ETHICS 286, 287, 290 (2008); see also Terry, *supra* note 14, at 697 (noting “concerns that many biobanks obtain and archive samples without the participants’ knowledge . . .”); Karen J. Maschke, *Returning Genetic Research Results: Considerations for Existing No-Return and Future Biobanks*, 13 MINN. J.L. SCI. & TECH. 559, 563 (2012) (“Anecdotal reports suggest that many medical research institutions control biobanks containing biospecimens that were obtained without consent for research or whose consent status is uncertain.”). Biospecimens and health data collected in the course of medical treatment might be used for research down the road, without participant consent. See ONORA O’NEILL, *AUTONOMY AND TRUST IN BIOETHICS* 42 (2003) (asking “[w]hat consent requirements, if any, are needed for secondary analyses of medical data collected without explicit consent in the course of previous treatment?”).

46. See *infra* Section II.B.1.

47. Fabsitz et al., *supra* note 15, at 576.

Joffe argue that it is the researchers' "privileged access to private information in the context of a consensual, professional relationship" that "trigger[s] and give[s] shape to obligations to respond to incidental findings": the "consented access to private health-related information in the context of a professional relationship" "gives rise to a [researcher's] duty to respond to incidental findings."⁴⁸ In Henry Richardson and Mildred Cho's similar formulation, individuals give up rights to privacy and bodily integrity when they voluntarily agree to participate in a research study; as a result, "researchers obtain special responsibilities" toward participants, which include "communicating a finding that may have a health impact."⁴⁹ The obligation of researchers to warn their participants of health risks uncovered in the course of research "attach[es] to the special permissions [that participants give researchers] to handle samples and associated data . . ."⁵⁰ The Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections likewise maintains that, since "[s]ubjects make an autonomous decision to participate in research, and in so doing help to create scientific knowledge that is valuable to society and to other individuals[.]" researchers can "provide recognition and appreciation for this contribution" by offering subjects "their individual information that results from the research."⁵¹

48. Franklin G. Miller, Michelle M. Mello & Steven Joffe, *Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants?*, 36 J.L. MED. & ETHICS 271, 275, 276-77 (2008) (emphasis added); see also *Managing Incidental Findings*, *supra* note 22, at 236 (mentioning that, if participants did not consent to the research, then given the "potential for surprise, it may be appropriate to limit attempts to contact [individuals] to [incidental findings] offering strong net benefit").

49. Henry S. Richardson & Mildred K. Cho., *Secondary Researchers' Duties to Return Incidental Findings and Individual Research Results: A Partial-Entrustment Account*, 14 GENETIC MED. 467, 468-69, 470 (2012) (quoting Illes et al., *supra* note 32, at 783); see also Miller et al., *supra* note 48, at 275-76 (advancing a similar reciprocity argument); Bartha Maria Knoppers & Ruth Chadwick, *Human Genetic Research: Emerging Trends in Ethics*, 6 NATURE REV. GENETICS 75, 75-76 (2005) (same). For a more detailed discussion of reciprocity- and gratitude-based arguments for the return of results, see generally Nina Varsava, *Human Subjects Research Without Consent: Duties to Return Individual Findings When Participation was Non-Consensual*, 20 AM. J. BIOETHICS 28 (2020).

50. Richardson & Cho, *supra* note 49, at 472; see also Illes et al., *supra* note 32, at 783 (asserting that the return of individual findings that may have a health impact serves to "demonstrat[e] reciprocity when subjects agree to participate in studies . . .") (emphasis added).

51. Sec'y's Advisory Comm. on Hum. Rsch. Prots., *Attachment B: Return of Individual Research Results*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (July 21, 2016), <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-return-individual-research-results/index.html>.

Some argue that the deeper or more extensive the relationship between the researcher and participant, the greater the researcher's duties with respect to the participant, including duties to return results. Describing this idea, Valerie Koch writes that "[t]he nature and duration of the relationship between the research participant and the investigator may be the most important consideration in determining whether investigators owe research participants a duty to disclose research findings."⁵² A 2018 "Consensus Study Report" issued by the National Academies of Science, Engineering, and Medicine with many contributors from a variety of disciplines similarly asserts that, "[g]enerally, . . . a deeper relationship between the investigator and participant gives rise to a greater responsibility to share results that may be of value to the participant."⁵³

Researchers will likely have more direct engagement with participants and so deeper relationships with them in the context of research with informed consent than without informed consent. Indeed, if researchers obtain and conduct studies on biospecimens or health data without informed consent, the researchers might have no direct engagement at all with participants.⁵⁴ Participants might not even be aware of the research relationship. A key implication of theories that ground duties of care in the depth of the researcher-participant relationship is that, if participants do not consent to the research at all, researchers will have minimal duties (perhaps none at all) with respect to them.

More generally, prevailing theories ground researchers' duties to return results in broader duties to respect participant autonomy

52. Koch, *supra* note 20, at 200.

53. NAT'L ACADS. OF SCIS., ENG'G & MED., RETURNING INDIVIDUAL RESEARCH RESULTS TO PARTICIPANTS 63 (Jeffrey R. Botkin, Michelle Mancher, Emily R. Busta & Autumn S. Downey eds., 2018); *see also* Morain et al., *supra* note 21, at 11 (suggesting that researchers who have little direct engagement with participants may have lesser obligations to disclose findings). Other commentators argue similarly that the larger the "range of permissions" or the greater discretion that participants grant to researchers with respect to the participants' data and biospecimens, the greater the scope of duties of care that the researchers owe to participants. Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care That Researchers Owe Their Subjects*, 34 HASTINGS CTR. REP. 25, 30 (2004); *see also* Laura M. Beskow & Wylie Burke, *Offering Individual Genetic Research Results: Context Matters*, SCI. TRANSLATIONAL MED., 30 June 2010, at 1, 1 (suggesting that duties to return individual results vary in proportion to the "scope of entrustment involved in the research").

54. This is the case for non-consensual research as well as research relying on "broad consent." I discuss the regulatory provision concerning broad consent below. *See infra* Section II.B.1.c.

and interests, and the latter duties in turn supposedly arise from the participant's voluntary contribution to the research. These theories thus give rise to recommendations to return results in the context of consensual research but suggest that researchers have lesser or no duties to return results if research was non-consensual.⁵⁵ But why would researchers have obligations to respect the autonomy and interests of participants only if their participation was willing and voluntary?⁵⁶ Part III, below, addresses this oversight in the literature; I argue that researchers have strong ethical reasons to return results even, and indeed especially, in the context of research without informed consent, and that the bioethics community ought to train its attention on this gap in the existing guidance.

2. Consent to the return of results

Even when researchers obtain participant consent to the research, they might not obtain consent to the return of results. This seems to have been the case with the Seattle Flu Study, where the researchers apparently did not inform participants that their samples might be tested for conditions other than influenza and that other results might be returned to them or reported to others.⁵⁷ The literature has been effectively silent on whether researchers should disclose results to participants in this kind of scenario. Prevailing recommendations state that researchers should return results to a participant if the participant has consented to receive them. But the recommendations generally do not specify whether researchers should return results *only* if a participant has consented to it.

55. Legal disputes about researchers' duties to inform participants about health risks have also turned on the issue of voluntary participation or consent. See *infra* Section II.B.1.a. Nevertheless, as I argue in section III.B, researchers might have some common law duties to return results even in non-consensual research under a theory of the duty to warn or rescue.

56. Reacting to efforts to ground duties to return results in reciprocity, Kelly Fryer-Edwards and Stephanie Fullerton raise the related question of why participants who "find themselves in a less intense research relationship" are less entitled to receive results, when these participants "have the same health-based interest in a given disclosure" and "the same preferences with respect to knowing a result." Kelly Fryer-Edwards & Stephanie M. Fullerton, *Relationships with Test-Tubes: Where's the Reciprocity?* 6 AM. J. BIOETHICS 36, 37 (2006). They argue that we need to attend to the "justice implications of relying on the duration and intensity of the relationship to make disclosure determinations." *Id.* Attending to those implications is part of this Article's aim.

57. See *supra* notes 1–8 and accompanying text.

For example, the NHLBI Group's guidelines provide that if researchers uncover individual, health-relevant results, then they should offer to return these results to participants *if* "[d]uring the informed consent process or subsequently, the study participant has opted to receive [their] individual genetic results."⁵⁸ Another large working group, assembled to "identify consensus recommendations" concerning the return of results to research participants, likewise concludes that, "when investigators have a valid research result that will allow preventive or other steps important to protect the participant's health, these data should be offered to identifiable research participants." The authors note that this idea has been widely endorsed.⁵⁹ But they assert that the conclusion is based on the "assum[ption] that the participant has consented to the return of results in the informed-consent process."⁶⁰ The group says nothing about the responsibility of researchers regarding the disclosure of results in the event that participants have *not* consented to disclosure upfront.

Some commentators assert that researchers are not permitted to disclose results if participants have not given informed consent to the disclosure. For example, a Canadian policy statement provides that, "[t]o respect the participants' autonomy, the communication of the findings determined to be material *can only be done* when participants or their authorized third parties have consented to receiving them initially or as part of the ongoing consent process."⁶¹ This prescription suggests that researchers may return results *only* if participants consented both to the research and to the disclosure of results.

One might contend that to avert this kind of dilemma, researchers could contact a participant who did not consent upfront to receiving individual findings and ask if they now wish to receive

58. Fabsitz et al., *supra* note 15, at 575.

59. Gail P. Jarvik, Laura M. Amendola, Jonathan S. Berg, Kyle Brothers, Ellen W. Clayton, Wendy Chun, Barbara J. Evans, James P. Evans, Stephanie M. Fullerton, Carlos J. Gallego, Nanibaa' A. Garrison, Stacy W. Gray, Ingrid A. Holm, Iftikhar J. Kullo, Lisa Soleymani Lehmann, Cathy McCarty, Cynthia A. Prows, Heidi L. Rehm, Richard R. Sharp, Joseph Salama, Saskia Sanderson, Sara L. Van Driest, Marc S. Williams, Susan M. Wolf, Wendy A. Wolf, eMERGE Act-ROR Comm. & CERC Comm., CSER Act-ROR Working Grp. & Wylie Burke, *Return of Genomic Results to Research Participants: The Floor, the Ceiling, and the Choices in Between*, 94 AM. J. HUM. GENETICS 818, 818, 821 (2014).

60. *Id.*

61. CAN. INSTS. OF HEALTH RSCH. et al., *supra* note 42, at 34 (emphasis added).

such findings. The appeal of this strategy, however, is largely superficial, because presenting the option to a participant in this way effectively amounts to informing them that an important health finding has been uncovered. And so, although a researcher in this context probably should ask the participant whether they wish to receive a result that has been discovered before disclosing the details, we should not presume that this gesture would solve the lack of advanced consent problem. As Stephanie Morain and coauthors explain, “[t]his issue has been deemed the problem of the ‘cold call,’” in which an unwitting participant gets a call out of the blue from a researcher informing the participant that the researcher possesses important information about the participant’s health and asks the participant whether they would like to hear it.⁶² At that point, the cat is already partly out of the bag.

Some groups recognize the critical gap in their prescriptions but offer only unsatisfying stopgap measures in response. For example, the NHLBI Group asserts that, if participants did not consent to the return of results in advance, then “researchers should consult with their IRB regarding the appropriateness of communicating individual [results]”⁶³ This suggestion merely passes the problem onto the IRB to resolve. In a report on the ethical management of individual findings in genomic research, an NIH-funded multidisciplinary working group acknowledges cases in which participants have not consented to the return of results, observing that in these cases “researchers or the biobank may nonetheless encounter findings of high health significance and actionability.”⁶⁴ The authors note that “how to handle return in this

62. Morain et al., *supra* note 21, at 11; *see also* Clayton, *supra* note 45, at 290 (observing that “[i]n most cases of genomics research using archived samples, the problem of the ‘cold call’ and the question that often follows—How can I say I do not want to know when someone says they have important information about me?—is unavoidable.”); Gail P. Jarvik et al., *supra* note 59, at 822 (suggesting that participants should be asked their preferences at the informed consent stage, since “[f]raming the conversation as ‘if we find . . . would you want’ avoids the potentially coercive ‘we have . . . do you want.’”).

63. Fabsitz et al., *supra* note 15, at 576.

64. Susan M. Wolf, Brittney N. Crock, Brian Van Ness, Frances Lawrenz, Jeffrey P. Kahn, Laura M. Beskow, Mildred K. Cho, Michael F. Christman, Robert C. Green, Ralph Hall, Judy Illes, Moira Keane, Bartha M. Knoppers, Barbara A. Koenig, Isaac S. Kohane, Bonnie LeRoy, Karen J. Maschke, William McGeeveran, Pilar Ossorio, Lisa S. Parker, Gloria M. Petersen, Henry S. Richardson, Joan A. Scott, Sharon F. Terry, Benjamin S. Wilfond & Wendy A. Wolf, *Managing Incidental Findings and Research Results in Genomic Research Involving*

scenario is [a] hard question.”⁶⁵ And they indicate that “an emerging recommendation is to allow some return, where possible, but only of the most important findings, that is, those [with strong net benefit].”⁶⁶ The authors seem to believe that researchers should be *permitted*, but not necessarily required, to return results if participants did not consent in advance to receive them. But the suggestion is vague, and no argument is provided to support it.

Bioethicists and biomedical researchers have extensively debated whether researchers should sometimes return health-relevant results, and have reached a consensus around the conclusion that they should. However, the literature simultaneously asserts a requirement to inform participants *ex ante* about the return of results and seems to assume that researchers will do so. Scholars have thus side-stepped the question of how health-relevant results should be handled in the event that participants were not given the opportunity upfront to consent to disclosure.

B. The Legal Landscape

What does the law have to say about disclosing results to participants who did not consent to the disclosure in advance? This section takes up that issue, focusing on the Common Rule, but also touching on related legal provisions.

1. The Common Rule

The set of regulations known as the “Common Rule” governs the consent process and related aspects of research involving human participants. It applies to research funded by federal agencies and was last updated in 2018, with a general compliance date of January 21, 2019.⁶⁷ The rule does not impose any affirmative duties on researchers to return results to participants, and even creates incentives for researchers *not* to return results.⁶⁸ This subsection

Biobanks and Archived Data Sets, 14 GENETICS MED. 361, 380 (2012) [hereinafter *Biobanks and Archived Data Sets*].

65. *Id.* at 372.

66. *Id.* at 380.

67. 45 C.F.R. § 46.116(l)(2) (2020). See *supra* note 9 for more details on the research covered by the Common Rule.

68. *Id.* § 46(a). Two articles focusing on biobank research discuss how federal regulations disincentivize the return of results by encouraging the de-identification of biospecimens and data, despite the strong ethical reasons supporting return in some cases.

analyzes the relationship between the return of individual results and consent requirements under the current Common Rule.

a. Informed consent. In the event that researchers opt for traditional informed consent, consent materials must include “[a] statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”⁶⁹ If researchers prefer not to, or are unable to, devise a plan for the return of results in advance of the study, then they might opt for a blanket statement indicating that results will not be returned. Such a statement might in turn create legal duties not to return results, even if the researchers later determine that they have moral reasons to return them. This is because returning results would violate the consent terms, possibly posing problems not only under the Common Rule but also under contract or tort law.

The Common Rule does require that the consent materials include “[a] statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject.”⁷⁰ This provision could be read to require researchers to return individual results under certain circumstances, although as far as I am aware neither officials nor biomedical researchers have interpreted it that way. In the vast majority of studies, it is difficult to see how receiving even highly concerning and actionable results would affect the participant’s willingness to participate. An exception, perhaps, would be studies involving substantial and ongoing participant engagement.

In the Maryland state case of *Grimes v. Kennedy Krieger Institute*⁷¹ (discussed at greater length below in this section), the court did suggest that “information that might bear on

McGeeveran et al., *supra* note 35, at 504–29; Leili Fatehi & Ralph F. Hall, *Enforcing the Rights of Human Sources to Informed Consent and Disclosures of Incidental Findings from Biobanks and Researchers: State Mechanisms in Light of Broad Regulatory Failure*, 13 MINN. J.L. SCI. & TECH. 575, 593–98 (2012). My analysis here of the regulatory scheme is consistent with and expands on the views presented in those articles.

69. 45 C.F.R. § 46.116(c)(8).

70. *Id.* § 46.116(c)(5).

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

[participants'] willingness to continue to participate in the study . . . includes . . . continuing warnings as to all the potential risks and hazards . . . that arise during the research."⁷² This study represents a special case, however, because the health risk that researchers uncovered (lead exposure) was tied to the research in such a way that participants could minimize or mitigate the risk by exiting the study. This is critically different from studies where researchers uncover health-relevant findings such as genetic abnormalities, which exist completely independently of the research and are neither created nor exacerbated by it.

The Common Rule does not create a private right of action, so a research participant cannot sue researchers under the rule for violations.⁷³ Researchers do face penalties for violations, however, including federal orders to stop the research and rescinding of federal funding.⁷⁴ Moreover, some scholars have suggested that a consent form creates a binding agreement between researcher and participant, and the researcher thus has a contractual duty to act in accordance with its terms.⁷⁵ For Elizabeth Pike and coauthors, "[a] clear and appropriate [legal] rule would require that researchers disclose in the informed consent document the extent to which [findings] will be returned to participants, with a corresponding legal duty to act in a manner consistent with the terms set forth in the informed consent document."⁷⁶ An implication of this proposal is that, if the consent document provides that results will not be

72. *Id.* at 843.

73. Koch, *supra* note 20, at 176, 186–90 (explaining the lack of a private right of action under the Common Rule and FDA regulations and asserting that, because a duty of care is not recognized in the regulations, "courts are generally reluctant to recognize a duty-conferring relationship between the investigator and research participant").

74. OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP) DEPARTMENT OF HEALTH AND HUMAN SERVICES, OHRP'S COMPLIANCE OVERSIGHT PROCEDURES FOR EVALUATING INSTITUTIONS (Oct. 14, 2009), <https://www.hhs.gov/ohrp/sites/default/files/ohrp/compliance/evaluation/ohrpcomp.pdf>; *see also* 45 C.F.R., § 46.123(a) (2020) ("The department or agency head may require that Federal department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy."); 21 C.F.R. § 56.121 (2019).

75. Elizabeth R. Pike, Karen H. Rothenberg & Benjamin E. Berkman, *Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomic Research*, 102 GEO. L.J. 795, 795 (2014).

76. *Id.* at 831.

returned, then not only will researchers have no legal duty to return them, but they will actually have a legal duty *not* to do so.

The Pike group does note that, if informed consent materials are silent on or inadequately address the return of results, “the general assumption should not be that researchers are therefore protected from legal liability”; instead, “courts should look carefully and skeptically at inadequate consent documents.”⁷⁷ The authors list some factors for courts to consider when evaluating a consent form and whether a researcher has a duty to return results. The primary factor is “whether and to what extent a research participant reasonably relied on a researcher to return [findings].”⁷⁸ If informed consent materials did not indicate that results would be returned, then a participant would have a hard time arguing that they reasonably relied on the return of individual results, especially since it is not the norm for researchers to return results.⁷⁹ Indeed, the authors explain that “[t]his factor could be satisfied by showing that the researcher (by word or action) explicitly took on a duty of disclosure on which it was reasonable for the participant to rely.”⁸⁰ Accordingly, under the Pike framework, researchers would be unlikely to have a legal duty to return results unless they informed participants in advance that results would be returned.

In the case of *Grimes*, the Maryland Court of Appeals (Maryland’s highest state court), determined that the plaintiffs’ consent to participate in a research study created duties of care on the part of the researchers, including a duty to return certain health-relevant results to participants.⁸¹ The *Grimes* defendant had conducted a study of lead abatement methods, which involved testing lead levels in the participant homes and in the children who lived there.⁸² The defendant had failed to notify participants, in a timely fashion, of dangerous levels of lead exposure, and the plaintiffs (several participants in the study) sued for negligence.⁸³ The Maryland court reasoned that the informed consent agreements “created contractual relationships imposing duties [of care],” which

77. *Id.* at 839.

78. *Id.* at 840.

79. *See infra* Section II.C.

80. Pike et al., *supra* note 77, at 840.

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

82. *Id.* at 811-12.

83. *Id.* at 818.

in turn could form the basis of a negligence action against the researchers.⁸⁴ According to the court, the consent form served as evidence that the participants agreed to participate “with the expectation that they would . . . receive promptly any information that might bear on their willingness to continue to participate in the study,” including “continuing warnings as to all the potential risks and hazards . . . that arise during the research.”⁸⁵ Indeed, the consent document specified that the researchers would share “specific blood-lead results,” and a plaintiff contended “that this agreement between the parties gave rise to a duty owed by [the researcher] to provide her with that information in a timely manner.”⁸⁶

Despite its emphasis on the contractual nature of the relationship, the court suggested that a “special relationship” between researcher and subject “giving rise to duties” might exist even in the absence of a contract and that the special relationship can arise out of state or federal “governmental regulations,” including the Common Rule.⁸⁷ Nevertheless, because the court heavily emphasized the consent materials and consensual interactions between the researcher and the participants, the reasoning of the opinion would not readily support a duty to return results in the absence of the consent agreement and participants’ reasonable expectations that they would receive results.⁸⁸ And so, while the *Grimes* case illustrates the possibility of a private right of action based on the failure of a researcher to disclose individual results to participants, it does not offer much fuel for a duty to disclose if participants did not consent to the return of results in advance, never mind if participants did not give informed consent to the research study itself.

84. *Id.* at 843.

85. *Id.*

86. *Id.* at 844.

87. *Id.* at 819. *But see* Koch, *supra* note 20, at 189 (observing that courts have “generally refused to find that the federal rules and regulations governing informed consent in research give rise to a private right of action for research participants”).

88. *But see* Fatehi & Hall, *supra* note 68, at 627 (quoting *Grimes*) (suggesting that the case “shows that state courts may derive and define the duties owed by the researcher to the human subject not just from the relationship created by, and terms of, the informed consent agreement, but from the privileged ability of researchers to ‘anticipate, discover, and understand’ their subjects’ potential health risks”).

b. Waiver of Informed Consent. The Common Rule allows researchers to obtain a waiver or alteration of consent requirements by their IRB if a number of conditions are met. These conditions include that “[t]he research involves no more than minimal risk to the subjects,” “[t]he research could not practicably be carried out without the requested waiver or alteration,” “[t]he waiver or alteration will not adversely affect the rights and welfare of the subjects,” and “[w]henever appropriate, the subjects . . . will be provided with additional pertinent information after participation.”⁸⁹

Individual health-relevant results could conceivably qualify as “additional pertinent information,” such that researchers who obtained a waiver may in some cases face an obligation to return individual results to participants after the study. There is no evidence, however, that researchers, IRBs, or agencies are interpreting the “additional pertinent information” provision in this way. On the contrary, IRBs sometimes grant waivers of consent only on the condition that researchers will *not* re-contact participants to disclose results.⁹⁰ And some scholars likewise maintain that researchers should not be permitted to waive consent if they anticipate recontacting participants to return results, since participants would have to be informed about the researchers’ intentions in advance.⁹¹

Researchers who obtain a waiver of the consent requirements, then, seem to have no regulatory duties to return results, and IRB conduct, as well as scholarly commentary, suggest that researchers may obtain a waiver only if they are *not* going to return results. The possibility of obtaining a waiver of consent

89. 45 C.F.R. § 46.116(f)(3) (2020).

90. See Ravitsky & Wilfond, *supra* note 44, at 12 (describing a study of “gene expression in breast biopsy specimens” in which “the IRBs waived the requirement to obtain participants’ consent to use their specimens, provided that investigators would not contact them with any results”); see also NAT’L ACADS. OF SCIS., ENG’G & MED., *supra* note 5344, at 60 (reporting that, “[h]istorically, institutional review boards (IRBs) have actively discouraged the disclosure of research results to individual participants apart from a few exceptional circumstances”). Some scholars indicate that their home IRBs do not allow researchers to contact former participants if those participants did not consent to participate in the research. See Clayton, *supra* note 45, at 286.

91. See Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J.L. Med. & Ethics 15, 20 (2005).

requirements might accordingly make researchers who would otherwise be inclined to return results less likely to do so.

c. Exemptions for secondary research. The Common Rule gives researchers the opportunity to sidestep the detailed informed consent requirements and instead obtain “broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.”⁹² The broad consent requirements are significantly less onerous than the informed consent ones.⁹³

The Common Rule section on Exempt Research indicates that researchers may enjoy exemption from other policy requirements by relying on broad consent only if (among other things) they do “not include returning individual research results to subjects as part of the study plan.”⁹⁴ In turn, the broad consent process requires participants to be informed that “clinically relevant research results” “may not be disclosed to [them]” “[u]nless it is *known*” that such results “will be disclosed to [them] in all circumstances.”⁹⁵ Given that researchers can rely on broad consent to exempt them from other regulatory requirements only if they do *not* have a plan to return results, it seems unlikely that at the point of obtaining broad consent researchers would know that results will be returned to participants in all circumstances. The exemption conditions make any such knowledge highly unlikely because they require researchers who wish to rely on broad consent and avoid other more demanding regulatory requirements to refrain from planning for the return of results – possibly even to cancel any intention they would otherwise have to return results.⁹⁶

92. 45 C.F.R. § 46.116(d).

93. Compare 45 C.F.R. § 46.116(d) (requirements for broad consent) with 45 C.F.R. § 46.116(a)–(c) (requirements for informed consent).

94. 45 C.F.R. § 46.104(d)(8)(iv) (emphasis added).

95. *Id.* § 46.116(d)(6) (emphasis added).

96. See Office for Human Research Protections, *Attachment C – Recommendations for Broad Consent Guidance*, HHS.GOV (July 26, 2017), <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html> (stating that to qualify for a broad-consent-based exemption, “the intention to return individual research results [cannot] be part of the study plan—that is, . . . the return of results [cannot be] a planned, premeditated activity contemplated in the protocol”).

Accordingly, researchers obtaining broad consent have a significant incentive not to obtain participant consent to the return of results and instead to inform participants that results may not be returned – effectively, to get participant consent for non-return. This approach helps protect them, and other researchers, from potential legal duties to return results uncovered in the course of secondary research, and enables them and others to proceed without any plan to return results and therefore to qualify for the broad-consent-based exemption from other regulatory requirements.

Congruent with the regulations, some bioethicists advise that if researchers do plan to return any individual results, then “detailed informed consent will be ethically and legally required.”⁹⁷ This kind of prescription gives researchers reason *not* to plan for or anticipate the return of results. Researchers who do not make a plan in advance to return results are less likely, ultimately, to return results than those who do make such a plan – since planning to do something generally makes it more likely that you will do the thing. That is the point of plans, after all! The Common Rule’s broad consent provision, then, together with its broad-consent-based category of exempt research, encourage researchers not to obtain participant consent to the return of results, not to plan to return results to participants, and ultimately not to return results to them.

In response to comments received through the notice and comment process, the Office for Human Research Protections (OHRP) itself stated that they recognize the concern that “this exemption does not provide an incentive to investigators to provide individual results to subjects.”⁹⁸ But OHRP insisted that

97. Clayton *supra* note 91, at 20; *see also* Ravitsky & Wilfond, *supra* note 44, at 15.

98. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7,199 (Jan. 19, 2017) (codified at 45 C.F.R. pt. 46). Many comments, to both the 2011 Advanced Notice of Proposed Rulemaking and the 2015 Notice of Proposed Rulemaking, expressed worries that if researchers who do not plan to return results may be exempt from full IRB review, that would create self-interested incentives for researchers not to return results. *See, e.g.*, Stacey Berg, Comment Letter on the Common Rule (Oct. 3, 2011) (“We would like to note that excusing use of existing biospecimens from IRB review unless the investigator plans to return results to subjects could create a disincentive for investigators to return results.”); Univ. of Wash. Ctr. for Genomics & Healthcare Equal., Comment Letter on the Common Rule (Oct. 24, 2011) (“under such a policy, sensible investigators would elect not to develop plans to return results”; “this approach [accordingly] creates an inappropriate disincentive to returning results that is particularly problematic for research with translational potential”); Ann Bonham, Comment Letter on Proposed Rule for Federal Policy for the Protection of Human Subjects (Jan. 4, 2016) (expressing concern that the rule “that deems research with stored biospecimens ineligible to be considered exempt if the investigator

“the challenges of how and when to return such results warrant consultation with the IRB” and that when researchers plan to return results, “it would almost always be appropriate for the study to be reviewed by an IRB”⁹⁹ It is not just that the terms of the exemption do not create an incentive for researchers to return results though. The terms actually disincentivize the return results, since they substantially reduce the regulatory burden for researchers who agree to refrain from anticipating the return of results.

Another category of exempt research under the Common Rule comprises “[s]econdary research uses of identifiable private information or identifiable biospecimens” in which (1) information “is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, [(2)] the investigator does not contact the subjects, and [(3)] the investigator will not re-identify subjects.”¹⁰⁰ An implicit condition of this exemption would seem to be that individual research results will not be returned to subjects, since that would require not only identifying but also contacting them.¹⁰¹

As other scholars observe, the regulations “strongly encourage secondary researchers who work with de-identified data to promise, in advance, that they will make no attempt to reidentify.”¹⁰²

anticipates returning research results to individual subjects . . . demonstrates neither respect for persons nor the facilitation of research”); Jennifer Wagner, Comment Letter on Proposed Rule for Federal Policy for the Protection of Human Subjects (Dec. 9, 2015) (expressing disappointment “with the language that would make it more difficult for researchers to engage in equitable research practices—specifically, language that can only be interpreted as an attempt to discourage researchers from returning research results to participants”).

99. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7,199.

100. 45 C.F.R. § 46.104(d)(4)(ii).

101. As McGeveran et al., *supra* note 35, at 513–14, 519, observe, the regulations “in many ways . . . discourage the return of findings”; “[i]n particular, the strong and increasing emphasis on robust deidentification standards generally deters return of results,” and “[i]nstead of providing any mechanisms to facilitate the return of results where it is otherwise justified, the [regulations] treat[] reidentification as categorically undesirable.” The authors argue that the rules “should specifically stipulate that return of individual research findings can be an ethically appropriate reason to reidentify specimens or data.” *Id.* at 530. See also Fatehi & Hall, *supra* note 68, at 593 (explaining that, “even when disclosures of IFs remain a [factual] possibility, the very act of considering them for disclosure or identifying their sources may trigger an uncertain and complex web of regulatory requirements”).

102. McGeveran et al., *supra* note 35, at 524. Focusing on the obligations of secondary researchers in the biobank research context, the authors explain how an exemption for de-identified materials encourages such researchers to “foreswear any . . . plans to re-contact contributors in order to avoid . . . administrative costs and delay to research,” and they

Researchers might even sever their own access to the information necessary to identify participants in an effort to qualify for the exemption, thereby making it impossible for them to contact participants in the event that individual health-relevant results are discovered.¹⁰³

2. Other rules

Other legal provisions create further incentives for researchers not to disclose health-relevant results to participants. Research laboratories are exempt from the Clinical Laboratory Improvement Amendments (CLIA) requirements, but only if they do not “report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients.”¹⁰⁴ If researchers wish to return individual results that meet the former description, then they would need to either have their lab CLIA certified and ensure that it meets CLIA requirements—which include maintaining detailed records on all “patients”; maintaining personnel with specific types of expertise, such as a technical consultant and clinical consultant; and carrying out annual evaluations of all activities—or else reproduce the

observe that both the Common Rule and HIPAA “encourage early and robust deidentification of specimens and data” and “[n]either promotes planning to reidentify those same specimens or data.” *Id.* at 524, 529; see also Fatehi & Hall, *supra* note 68, at 628–29 (“The recognition of duties arising from the ability of researchers to foresee or identify information of health significance to research participants is a factor that is especially significant in the context of secondary research on archived specimens and DNA information because the very purpose of such secondary research is often to establish the link between particular conditions and the traits thought to be associated with those conditions.”).

103. See McGeeveran et al., *supra* note 35, at 518, 528 (noting that some biobanks “eradicate the return path intentionally,” “irretrievably deidentify[ing] specimens and data, [and thus] making reidentification impossible”); Fatehi & Hall, *supra* note 68, at 581 (“Some biobanks deliberately and permanently de-identify specimens and data prior to sharing them with downstream secondary researchers so that no obligations to human sources may exist”; as a result, “secondary researchers may not have any contact with the human sources and may not know or be able to determine the sources’ identities.”). Note that the Common Rule governs only research involving human subjects as defined in the policy and that definition excludes research using human data or specimens that are not identifiable; accordingly, if the connection between the individual and the data or specimen is actually irreversibly severed then research using the material would not be regulated under the policy. 45 C.F.R. §§ 46.101(a), 46.102(e)(1).

104. 42 C.F.R. § 493.3(b)(2).

results in a CLIA-certified lab.¹⁰⁵ Otherwise, the researchers could be subject to severe sanctions, including fines and imprisonment.¹⁰⁶

As we can see then, although the law and policy governing human subjects research allows researchers to commit themselves to returning individual results, it does not require them to make any such commitment, and in multiple ways imposes obstacles to the return of results. By offering incentives to researchers who do not plan to disclose results to participants, the regulations make it less likely that researchers will seek participant consent to disclosure, and in turn less likely that researchers will be legally required or even permitted to disclose results that they uncover in the course of research.¹⁰⁷

C. *The Practice*

Although researchers do sometimes offer participants individual results, in general “[human subjects] researchers have recognized no responsibility to communicate clinically important information [to participants].”¹⁰⁸ A 2012 nation-wide survey study

105. *Id.* §§ 491.10, 493.1409, 493.1415, 493.1453, 491.11.

106. *Id.* § 493.1800. There is a debate in the literature about whether research labs that return individual health-relevant findings are subject to CLIA. See Jarvik et al., *supra* note 59 at 819, 822–24 (discussing the CLIA debate and concluding that “[f]urther work is needed on the role of CLIA compliance in the return of research results.”). Some commentators interpret CLIA as applying to such research labs. See, e.g., NAT’L ACADS. OF SCIS., ENG’G. & MED., *supra* note 53, at 28 (recognizing a “current absolute prohibition on the return of research results from non-CLIA-certified laboratories”). Others disagree. See, e.g., Barbara J. Evans & Susan M. Wolf, *A Faustian Bargain That Undermines Research Participants’ Privacy Rights and Return of Results*, 71 FLA. L. REV. 1281, 1318 (2019) (arguing that research labs are exempt from CLIA requirements because when researchers return individual findings it is not for a direct clinical purpose). It is beyond the scope of this Article to wade into this CLIA debate, but in my opinion the more reasonable interpretation is that CLIA will typically apply to research labs that return individual results, since the purpose of returning these results is generally, even if indirectly, “for the diagnosis, prevention or treatment of . . . disease or impairment of, or the assessment of the health of individual patients.” 42 C.F.R. § 493.3(b)(2).

107. The Health Insurance and Portability and Accountability Act (HIPAA) gives individuals the right to access, at their own initiative, personal information about them contained in health records that HIPAA-covered entities (health care providers and associated entities) maintain about them; accordingly, if a research finding is documented in an individual’s health record, then the individual would have access to it under HIPAA. 45 C.F.R. § 164.524.

108. Wolf, *supra* note 38, at 443; see also NAT’L ACADS. OF SCIS., ENG’G. & MED., *supra* note 53, at 67 (“Individual research results are commonly not returned to participants despite a growing body of literature demonstrating that many participants are interested in receiving their results.”). It is difficult to determine what proportion of human subjects research includes information about the return of individual findings in consent materials. A 2004

of biobanking in the United States found that, of biobanks that have access to identifying information of participants, less than twenty percent return individual results.¹⁰⁹ Another study found that, of the biobanks that address return of results at all, “33–46% had documents saying they *do return* some information.”¹¹⁰ The inclusion of a blanket statement in the original consent form to the effect that individual results will not be disclosed seems to be a popular strategy.¹¹¹ It should not be surprising that researchers often decide not to return individual results, given the state of the law and policy analyzed in the previous section.

And yet, evidence overwhelmingly suggests that people want to receive individual results and that they view these results as highly

survey of imaging studies found that four out of six consent forms examined were silent on the issue of incidental findings. Judy Illes, Matthew P. Kirschen, Kim Karetsky, Megan Kelly, Arnold Saha, John E. Desmond, Thomas A. Raffin, Gary H. Glover & Scott W. Atlas, *Discovery and Disclosure of Incidental Findings in Neuroimaging Research*, 20 J. MAGNETIC RESONANCE IMAGING 743–47 (2004).

109. Gail E. Henderson, Teresa P. Edwards, R. Jean Cadigan, Arlene M. Davis, Catherine Zimmer, Ian Conlon & Bryan J. Weiner, *Stewardship Practices of U.S. Biobanks*, 5 SCI. TRANSLATIONAL MED. 1, 2 (2013); *see also* R. Jean Cadigan, Teresa P. Edwards, Dragana Lassiter, Arlene M. Davis & Gail E. Henderson, “*Forward-Thinking*” in U.S. *Biobanking*, 21 GENETIC TESTING & MOLECULAR BIOMARKERS 148, 150 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5367905/> (finding, through a survey study of 327 U.S. biobanks, that 57% have policies stating that results will never be returned); Laura A. Siminoff, Maureen Wilson-Genderson, Maghboeba Mosavel, Laura Barker, Jennifer Trgina & Heather M. Traino, *Confidentiality in Biobanking Research: A Comparison of Donor and Nondonor Families’ Understanding of Risks*, 21 GENETIC TESTING & MOLECULAR BIOMARKERS 171, 175 (2017) (“Currently, few large-scale genomic research projects in the United States routinely return results to participants.”).

110. *Biobanks and Archived Data Sets*, *supra* note 64 at 365 (emphasis added).

111. *See* Karen J. Maschke, *supra* note 45, at 561 (“The limited empirical data regarding biobanks in the U.S. suggest that most biobanks use the no-return approach.”); Alessi, *supra* note 23, at 1708 (“[M]any biobanks explicitly prohibit returning any [individual] results and inform research participants of this prohibition upon the initial submission of their biological materials.”). For example, a cluster of U.S.-based cancer trial groups has adopted a common consent template for biobank participation that includes a provision specifying that, “Research results will not be returned to you or your doctor.” Gloria M. Petersen & Brian Van Ness, *Returning a Research Participant’s Genomic Results to Relatives: Perspectives from Managers of Two Distinct Research Biobanks*, 43 J.L. MED. & ETHICS 523, 526 (2015); *see also* McGeeveran, Fatehi & McGarraugh, *supra* note 35, at 525 n.201 (citing an FAQ document from a national biobank, which provides that participants “will not receive any information from [their] donated samples” and “will not receive results on the research performed using [their] samples”). By some accounts, most biobank contributors globally “have signed consent forms [indicating] that they will not be contacted.” Donna M. Gitter, *The Ethics of Big Data in Genomics: The Instructive Icelandic Saga of the Incidentalome*, 18 WASH. U. GLOB. STUD. L. REV. 351, 358 (2019).

valuable to them personally. As Miller and David Shalowitz report, “[p]articipants consistently indicate that they are interested in receiving research results, in spite of transient distress that communication of results sometimes elicits.”¹¹² Carmen Breitkopf and coauthors found, through a survey study investigating preferences about the return of results (including a sample of actual biobank participants as well as a control sample of the general population), that over ninety-six percent of respondents would want to be informed of individual “medically useful” genetic results.¹¹³

Many people wish to receive even results that do not meet my threshold for health relevance.¹¹⁴ A study of participants in neuroimaging research found that over ninety percent of participants “would want to be informed of an incidental finding regardless of its significance.”¹¹⁵ In the Breitkopf group’s survey study, over fifty percent of people believed that a result “definitely [should] be offered” even if it indicates only a “small chance of developing disease.”¹¹⁶ Over eighty percent agreed that “results showing an increased risk for a disease that could be prevented or passed to children and a result providing information a person can

112. D. I. Shalowitz & F. G. Miller, *The Search for Clarity in Communicating Research Results to Study Participants*, J.L. MED. & ETHICS, Sept. 2008 at 1, 1; see also Mildred K. Cho, *Understanding Incidental Findings in the Context of Genetics and Genomics*, 36 J.L. MED. & ETHICS 280, 281 (2008) (“Empirical research suggests that participants want to know individual research results”); Miller et al., *supra* note 48, at 277 (“Empirical research suggests that few subjects would choose not to receive findings.”); Clayton, *supra* note 45, at 288 (reporting that “research participants often want and even feel entitled to receive their results”).

113. Carmen Radecki Breitkopf, Gloria M. Petersen, Susan M. Wolf, Kari G. Chaffee, Marguerite E. Robinson, Deborah R. Gordon, Noralane M. Lindor & Barbara A. Koenig, *Preferences Regarding Return of Genomic Results to Relatives of Research Participants, Including After Participant Death: Empirical Results from a Cancer Biobank*, 43 J.L. MED. & ETHICS 464, 467 (2015); see also Juli Murphy, Joan Scott, David Kaufman, Gail Geller, Lisa LeRoy & Kathy Hudson, *Public Expectations for Return of Results from Large-Cohort Genetic Research*, 8 AM. J. BIOETHICS 36, 41 (2008) (finding that focus group participants have a “strong interest in receiving individual genetic research results”); Megan Fong, Kathryn L. Braun & R. Mei-Ling Chang, *Native Hawaiian Preferences for Informed Consent and Disclosure of Results from Genetic Research*, 2006 J. CANCER EDUC. S47 (finding that, “[m]ost respondents wanted results reported to them (87.6%)”); Kenji Matsui, Reidar K. Lie, Yoshikuni Kita & Hirotsugu Ueshima, *Ethics of Future Disclosure of Individual Risk Information in a Genetic Cohort Study: A Survey of Donor Preferences*, 18 J. EPIDEMIOL. 217, 219 (2008) (finding that an overwhelming majority of participants “wished to be recontacted if any genetic risk information of clinical significance should be discovered”).

114. See *supra* Section I.A.

115. Matthew P. Kirschen, Agnieszka Jaworska & Judy Illes, *Subjects’ Expectations in Neuroimaging Research*, 23 J. MAGNETIC RESONANCE IMAGING 205, 207 (2006).

116. Breitkopf et al., *supra* note 113, at 471.

act on definitely should be offered,” and over sixty-eight percent believed “that researchers should offer results to participants, no matter how much money it costs [the researchers].”¹¹⁷ Studies suggest that people have strong preferences in favor of receiving individual results, across various types of biomedical research. These preferences in themselves do not demonstrate that researchers should disclose results, but they do weigh in favor of that conclusion.

In the next section, I argue on ethical grounds that researchers should, under certain circumstances, return individual, health-relevant results to participants. And I suggest further that the ethical reasons to return results may be even stronger in cases where participants did not consent to the return in advance. In light of my ethical analysis, I suggest that the law should at least not prevent or discourage the disclosure of individual health-relevant results, even if it should not necessarily impose affirmative duties on researchers to disclose them.

III. THE REASON TO RETURN RESULTS

In focusing on settings in which researchers addressed the return of results during the informed consent process, bioethicists have tended to avoid some of the toughest questions about researchers’ duties to return individual results. I agree with the consensus view that it would be best to inform participants upfront, at the consent stage, about the return of results. But by grounding duties and permissions to return results in the consent process, many scholars have suggested, whether explicitly or implicitly, that researchers have lesser or no duties to return results in no-consent-to-return cases; this kind of argument thus neglects the rights and interests of the many research participants who are not given the opportunity *ex ante* to consent to the return of results.

My target of analysis here is not the ethical or legal status of different approaches to consent, but rather the status of different decisions regarding the return of results. I therefore largely refrain from ethical or legal judgments about the consent process itself. Instead, recognizing that researchers in fact employ various approaches to consent, I evaluate decisions concerning the return of results in light of those different approaches. I find that

117. *Id.* at 469, 471.

researchers have strong ethical reasons to return health-relevant results regardless of consent setting. To support this claim, I present several analogous contexts in which experts have duties, ethical and sometimes legal too, to warn individuals of dangers when those individuals are unlikely to learn about the dangers through alternative channels, and even if no consent to the warning was obtained. This kind of responsibility is not domain specific: we should not make a policy exception for biomedical researchers.

A. *The Ethics of Informing*

In a variety of contexts, we are subject to warnings from experts and public officials to which we did not consent. Sometimes, but not always, we are given the opportunity to opt out of such warnings.

For example, in 2013, the American College of Medical Genetics and Genomics (ACMG) issued a guidance statement providing that clinical laboratories performing genetic sequencing should search for a variety of medically actionable pathogenic variants and affected individuals should be informed of the results even if they did not seek testing for those variants.¹¹⁸ Laboratories were to analyze and report results for a host of specific genes, which “were selected based on substantial clinical evidence that pathogenic variants result in a high likelihood of severe disease that is preventable if identified before symptoms occur.”¹¹⁹ As Amy McGuire and coauthors explain,

118. Robert C. Green, Jonathan S. Berg, Wayne W. Grody, Sarah S. Kalia, Bruce R. Korf, Christa L. Martin, Amy L. McGuire, Robert L. Nussbaum, Julianne M. O’Daniel, Kelly E. Ormond, Heidi L. Rehm, Michael S. Watson, Marc S. Williams & Leslie G. Biesecker, *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 *GENETICS MED.* 565, 573 (2013) (recommending “that when a report is issued for clinically indicated exome and genome sequencing, a minimum list of conditions, genes, and variants should be routinely evaluated and reported to the ordering clinician” and “that these findings be reported without seeking preferences from the patient and family”).

119. ACMG Board of Directors, *ACMG Policy Statement: Update Recommendations Regarding Analysis and Reporting of Secondary Findings in Clinic Genome-Scale Sequencing*, 17 *GENETICS MED.* 68, 68 (2015) (<https://www.nature.com/articles/gim2014151>). The original ACMG guidelines, however, have received criticism from the bioethics community. See, e.g., Susan M. Wolf, George J. Annas & Sherman Elias, *Patient Autonomy and Incidental Findings in Clinical Genomics*, 340 *SCI.* 1049, 1049 (2013) (suggesting that “[t]he ethical and legal problems raised [by the guidance] are profound”). The year after issuing the 2013 guidelines, the ACMG walked them back somewhat, adding an opt-out provision. Press Release, Am. Coll. of Med. Genetics & Genomics, ACMG Updates Recommendation on “Opt Out” for Genome Sequencing Return of Results (Apr. 1, 2014) (https://www.acmg.net/docs/Release_ACMGUpdatesRecommendations_final.pdf). The guidelines now provide that, “[a]t the time of testing, the patient should be made aware that, regardless of the specific indication

“[t]he recommendations essentially argue that laboratory personnel have a professional obligation to conduct a comprehensive evaluation of available test results to identify such clinically significant findings.”¹²⁰ The obligation falls to clinical laboratories because of their professional position and expertise: they have special knowledge of what kind of genetic information is likely to be important to individual health and a special ability to uncover this information.¹²¹ The authors explain further that the same “ethical standard already governs clinical genetics practice”: “if a patient is being evaluated for a . . . cardiac condition [for example], practice standards . . . dictate that [the geneticist] should take . . . a family history and search for patterns that reveal genetic predisposition to [other diseases],” and communicate any findings to patients.¹²²

Further, in various scenarios outside the health care context we accept non-consensual disclosures or warnings as ethically appropriate and even required. For example, we receive alarming alerts on our phones when there has been criminal activity nearby, or if we happen to be in a location that is likely to be affected by a dangerous weather event such as a flood or tornado. Perhaps we would rather not know that an armed robbery has been committed in our community or that our neighborhood is likely to be affected by severe flooding. However, given that we might not otherwise learn of the danger until it is too late to act to mitigate or avert it, officials have determined that they are at least permitted, if not required, to deliver the warning. People may well find these warnings to be obnoxious, annoying, or unnecessarily alarming, but no one suggests (as far as I know) that they are unethical or that it is inappropriate to subject people to them as a default.

One might object that alerts about criminal activity or weather conditions are materially different because they are not personal in the way that individual health results are. Although the former

for testing, laboratories will routinely analyze the sequence of a set of genes deemed to be highly medically actionable so as to detect pathogenic variants that may predispose to a severe but preventable outcome”; patients should also be informed “that, if desired, they may opt out of such analysis”; “[h]owever, they should also be made aware at that time of the ramifications of doing so.” ACMG Board of Directors, *supra*, at 69.

120. Amy L. McGuire, Steven Joffe, Barbara A. Koenig, Barbara B. Biesecker, Laurence B. McCullough, Jennifer S. Blumenthal-Barby, Timothy Caulfield, Sharon F. Terry & Robert C. Green, *Ethics and Genomic Incidental Findings*, 340 *Sci.* 1047, 1047 (2013).

121. McGuire et al., *supra* note 120.

122. *Id.*

types of warnings typically are impersonal, they certainly could be personal—and making them so would not seem to affect their acceptability. For example, suppose that an accident at an industrial site results in high levels of chemicals in the air that are dangerous for only specific groups of people—say, people with asthma over the age of seventy-five or infants with respiratory issues. There may be very few people in the affected area who fall into these categories. Nevertheless, I suspect that people would generally find it appropriate for residents to receive alerts about the danger. The alerts might even be targeted such that only individuals most likely to be affected would receive the alert, so as not to unnecessarily alarm others. In this case the warning, and the threat, are highly personal. Moreover, the risk is health related, just like individual results uncovered in research. This kind of alert actually raises privacy and confidentiality concerns that are not present to the same extent in the return-of-results context, since individuals who receive the alert might be able to infer the identity of others who are subject to the risk, whereas in the context of human subjects research, a participant would receive a warning about an individual risk but others would not be informed of the risk to the affected person.

One might object further that warnings about environmental hazards are delivered by the government, and it is within the government's role, or the scope of the government-citizen relationship, to promote the well-being of citizens and sometimes even act paternalistically toward them, and so certain acts of warning are justified if carried out by the government but not other individuals or entities. For example, perhaps the government is permitted, even required, to compel residents to get certain vaccinations, but health professionals themselves could not exercise that kind of control over people. Suppose, though, that the government is not even aware of some danger—for example, a health hazard associated with an industrial site. Maybe environmental researchers discovered the hazard and were able to identify the individuals who might be affected by it; affected individuals might include not only nearby residents, but also people working at the site and in the vicinity. In that scenario, it seems that researchers should inform individuals who are at risk, even if that would require relatively intrusive forms of notification, such as leaving informational materials on people's car windshields, at their

homes, or even approaching them directly with the information. That the researchers are not government actors would seem to make little or no moral difference to the analysis.

Many similar scenarios can be imagined. For example, suppose a retired meteorologist sells handmade jewelry on a beach in a resort town. Suppose that, as a result of her expertise, the meteorologist knows that there is a good chance that a severe storm will hit the beach or that dangerous waves or currents will be present in the ocean. It would seem to be unobjectionable, and indeed morally praiseworthy if not required, for the weather expert to warn her customers, even though they did not consent to such a warning and even if they might prefer to remain ignorant. And the fact that the meteorologist's weather-related expertise is completely outside the scope of the relationship between her and her customers does not change the ethical analysis. Indeed, the relationship that the meteorologist has with her customers seems to be beside the point. It may be easier for her to warn her customers, since she is in direct communication with them, and that might mean that she has a stronger duty to warn them than others on the beach. However, I would think that the meteorologist should make some kind of effort to warn others as well. It is not a pre-established relationship between the expert and other individuals that gives rise to a moral duty or at least reason to warn, but rather the expert's knowledge, the asymmetry of her knowledge and the knowledge of others, and the potential benefit that sharing her knowledge is likely to have for them.¹²³ One might insist that an off-duty meteorologist is not obligated to inform anyone about meteorological dangers, because that would be asking too much of her; even if morality is not so demanding, however, we can still accept that the meteorologist would be praiseworthy for sharing her information with others in

123. Haavi Morreim, who was commissioned to write "a paper on the philosophical perspectives and ethical underpinnings for the return of individual-specific research results from research laboratories" for inclusion in the National Academies' guide on returning individual research results, makes a similar point in that paper. NAT'L ACADS. OF SCIS., ENG'G. & MED., *supra* note 53, at 354 ("[T]he main reason the investigator may have a specific, personal duty to return an [individual finding] need not rely on any sort of professional relationship or privileged access. It is enough that (1) the investigator is among the few who will actually see the relevant data and (2) the investigator may be the only one who will recognize the significance of such data for the individual research subject."); see also Beskow & Burke, *supra* note 53, at 1 (suggesting that in some (very limited) circumstances researchers will have a duty to disclose individual results grounded in the general duty to rescue).

an effort to prevent harm to them. In that case, the act would be supererogatory, which is to say “morally good although not (strictly) required.”¹²⁴

More generally, we tend to take for granted that people who have a special ability to help others in certain ways as a result of their training and expertise have a responsibility to actually help others in that way, even when the help is outside the scope of their relationship with those who would benefit from it, and even in circumstances when they are not otherwise acting in their professional capacity. For example, we expect physicians to help others in medical emergencies in both public and private settings, even when they are off duty. Although less well-established, I would think that lawyers have a similar responsibility to help an individual in a “legal” emergency. For example, if a lawyer witnesses an individual receiving a deportation order from a government official and it seems that the individual might believe that she must proceed to leave the country as soon as possible, then the lawyer should inform her that she has legal options, including the right to contest the order.¹²⁵ Experts carry their expertise with them even when they are not on the job, and the privilege of possessing special knowledge and skill comes with responsibilities to help others, people who do not possess the same knowledge or skill, but whose well-being may depend on it.

Sharing information in these situations matches individual need with benefit. In the context of human subjects research, for many participants no individual results will be uncovered, but through their participation all individuals would get the benefit of some probability of receiving important health results.¹²⁶ Those

124. David Heyd, *Supererogation*, in *THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY* (Edward N. Zalta ed., Winter 2019 ed.) <https://plato.stanford.edu/archives/win2019/entries/supererogation/>.

125. *Deportation*, USAGOV, <https://www.usa.gov/deportation> (last updated Aug. 18, 2021) (explaining that an individual who receives a deportation order can appeal the order and can also “file a complaint with the Department of Homeland Security” if the individual “feel[s] that [their] civil rights have been violated in the immigration, detention, or removal proceedings”).

126. For this reason, a policy in favor of returning individual results, should they arise, helps researchers to meet the demands of the principle of justice in the bioethics context, which requires that those who participate in the research, or their communities, stand to benefit from the research conducted rather than the benefits accruing mainly or only to, for example, better-off populations. See, e.g., Ruqaiyah Yearby, *Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study*, 67 CASE W. RES. L. REV. 1171, 1183 (2017)

who stand to benefit the most from the return of results would be the ones to receive them. Researchers are in a privileged and possibly even unique position to offer a benefit in the form of important health results. Indeed, a study might be the participants' only chance to receive the type of individual results that the researchers uncover. In this sense, the warning is not a fungible commodity. Individuals might not be able to obtain the information through other means, even if they were willing and able to pay for it. This was the case with COVID-19, for example, when the demand for testing far exceeded capacity.¹²⁷ The special and sometimes unique access that researchers have to individual results contributes to the moral reason that researchers have to offer this type of benefit in particular to participants.

As Ernest Weinrib argues, we should keep the duty to warn or rescue distinct from "the broader duty of beneficence": "In the rescue context," he explains, "the resource to be expended (time and effort directed at aiding the victim) cannot be traded on the market, and no administrative scheme could be established to ensure the socially desirable level of benefits."¹²⁸ This helps to explain why researchers could not fulfill their obligations to participants by paying them the monetary equivalent of the return of results. There may not be any monetary equivalent because there may be no way for participants to pay other actors to find and disclose the same results on the same timeline.

Compared to the analogous scenarios discussed here, the human subjects research context may present the strongest case for a duty on the part of experts to disclose information that could benefit the recipients. This is because researchers might owe participants the information not only as a result of the researchers' expertise and unique access to important information, but also because the researchers are indebted to participants for their contribution to research, whether that contribution was knowing and voluntary or not—and perhaps especially if it was not, as I explain below.¹²⁹

(explaining that the bioethics principle of justice requires that if a population serves as research subjects for the studies, that population should receive a benefit from the research).

127. See *supra* note 11.

128. Ernest J. Weinrib, *The Case for a Duty to Rescue*, 90 *YALE L.J.* 247, 272 (1980).

129. See *infra* Section III.D.

By returning results to participants, researchers show not only that they care about participants' wellbeing, but also that they respect participants' autonomy and right to be informed of available information that concerns their own health.

B. The Law of Informing

In the U.S., unlike in many other countries, we have no general legal duty to warn through the provision of information, nor do we have a general legal duty to rescue or aid those we know are in danger.¹³⁰ But we do have some legal duties to help others who are in danger or at risk. The duty arises most often in the context of certain pre-existing relationships, but the relationship can be minimal and fleeting, and the risk need not be a product of the relationship. For example, the operators of "common carriers," such as buses and trains, have a duty to help a passenger who is in danger, even when the danger was not caused by the common carrier and would have affected the individual wherever they happened to be at the time.¹³¹ As Claire Radcliffe explains,

[I]t is the rescuer's ability to rescue coupled with the victim's dependency on the rescuer that gives rise to the duty [to aid or rescue]. . . . In such a situation, the defendant is thought to hold some power or control over the plaintiff since "the defendant has the opportunity to take certain precautions to decrease the probability that harm will come to the plaintiff."¹³²

130. For a detailed discussion about the state of the law in the U.S., see Zachary Kaufman, *Protectors of Predators or Prey: Bystanders and Upstanders amid Sexual Crimes*, 92 S. CAL. L. REV. 1317 (2019). Kaufman notes that, although there is no general federal law requiring bystanders to crimes or other crises to report the situation to authorities or help victims directly, such "Bad Samaritan" laws do "exist in one form or another in the majority of states": five states have some kind of legal duty to rescue, but only three of these apply to non-criminal causes of harm, and the harm must be "grave" and "physical." *Id.* at 1344-47.

131. See, *Searcy v. Interurban Transp. Co.*, 179 So. 75 (1938) (holding that a transportation company is liable for failing to secure medical attention for an ill bus passenger even though the carrier did not cause the passenger's condition); *Coates v. Wash. Metro. Area Transit Auth.*, 297 F. Supp. 3d 69 (holding that a bus driver has a duty of care to the bus passengers to take measures to protect them from the criminal conduct of others); see also RESTATEMENT (SECOND) OF TORTS § 344 (explaining that businesses have a duty of reasonable care to persons exposed to risks from the conduct of third parties on business premises).

132. Claire Elaine Radcliffe, *A Duty to Rescue: The Good, the Bad and the Indifferent – The Bystander's Dilemma*, 13 PEPP. L. REV. 387, 395-96 (1986) (quoting Note, *The Duty to Rescue in Tort Law: Implications of Research on Altruism*, 55 IND. L.J. 551, 553 (1980)).

The Restatement of Torts lists numerous types of relationships that may give rise to a duty to aid or warn and suggests that there may be yet other relations beyond those listed that come with such a duty.¹³³ The Restatement notes further that “[t]he law appears . . . to be working . . . toward[s] a recognition of the duty to aid or protect in any relation of dependence”¹³⁴ And, as other scholars have observed, “courts have . . . opened the door to a [duty to disclose] for researchers”¹³⁵

In the case of *Grimes*, the court relied on the contractual relationship between researcher and participant as the central basis for the duty to inform participants of health-relevant results. But the court also suggested that such a duty might arise even in the absence of a contract: “A special relationship giving rise to duties, the breach of which might constitute negligence, might also arise because, generally, the investigators are in a better position to anticipate, discover, and understand the potential risks to the health of their subjects.”¹³⁶ And other courts have held that “[a] duty to warn exists when there is ‘unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given.’”¹³⁷ A Federal District Court determined that a hospital physician who was in charge of a program to research the effects of a radiation treatment that had been given to the hospital’s former patients had a duty to inform individuals about negative effects of that treatment, even though he had never had physician-patient relationships with them.¹³⁸

133. RESTATEMENT (SECOND) OF TORTS § 314A; RESTATEMENT (THIRD) OF TORTS § 40.

134. RESTATEMENT (SECOND) OF TORTS § 314A, caveat & cmt. B; *see also* RESTATEMENT (THIRD) OF TORTS § 40 (asserting that certain “special relationships” give rise to duties of care and that “the term ‘special relationship’ has no independent significance[.]” but “merely signifies that courts recognize an affirmative duty arising out of the relationship where otherwise no duty would exist”; and explaining that “[w]hether a relationship is deemed special is a conclusion based on reasons of principle or policy[.]” and “[n]o algorithm exists to provide clear guidance about which policies in which proportions justify the imposition of an affirmative duty based on a relationship”).

135. Gordon, *supra* note 35, at 226.

136. *Grimes*, 782 A.2d at 851. For a discussion of the *Grimes* case, see *supra* Section II.B.1.a.

137. *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 805 (N.D. Ill. 1999) (quoting *Kokoyachuk v. Aeroquip Corp.*, 526 N.E.2d 607, 610 (Ill. App. Ct. 1988)). See *Fatehi & Hall*, *supra* note 68, at 627–29, for a discussion of the case and its implications for duties of researchers to return results.

138. *Blaz*, 74 F. Supp. 2d at 806–07.

“[P]lacing the burden [to inform] on the [researcher/physician] . . . is the only decision that makes sense,” the judge explained, “since Dr. Schneider was in a special position to acquire the information and had in fact done so, while [the plaintiff] was in no position to find out.”¹³⁹ Likewise, in *Safer v. Pack*, the Superior Court of New Jersey determined that a physician who possesses knowledge about a patient that has significant health implications for family members of the patient will sometimes have a duty to inform the family members, even if they are not his patients.¹⁴⁰ In this case, the patient had a life-threatening and possibly preventable genetic disease, and the physician knew or should have known that the patient’s child would be at substantial risk of developing the disease.¹⁴¹

Turning to a different medical context, clinical psychologists who learn that their own patients are a danger to third parties have a legal duty to warn those in danger. This duty was first and most famously recognized in the case of *Tarasoff v. Regents of the University of California*, where the California Supreme Court held that, “[w]hen a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger.”¹⁴² As Béatrice Godard explains, “[t]he duty to warn [in the *Tarasoff* scenario] has been interpreted as a duty to act to prevent foreseeable harm.”¹⁴³ The reasons *against* warning in a case like

139. *Id.* at 806.

140. *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) (“declin[ing] to hold . . . that, in all circumstances, the duty to warn will be satisfied by informing the patient[.]” and asserting that “[w]e see no impediment, legal or otherwise, to recognizing a physician’s duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition.”). The New Jersey legislature, however, responded to this decision with a statutory amendment that would seem to impose such a legal impediment. See New Jersey Genetic Privacy Act, Pub. L. 96, ch. 126 (Nov. 19, 1996) (codified as N.J. Stat. § 10:5-44(2)(b)) (providing that “[g]enetic information is personal information that should not be . . . disclosed without the individual’s authorization.”)

141. *Safer*, 677 A.2d at 1190.

142. *Tarasoff v. Regents of the Univ. of Cal.*, 17 Cal. 3d 425, 431 (1976).

143. Béatrice Godard, Thierry Hurlimann, Martin Letendre, Nathalie Égalité & INHERIT BRCA, *Guidelines for Disclosing Genetic Information to Family Members: From Development to Use*, 5 FAMILIAL CANCER 103, 105 (2006). Thomas Murphy suggests that a lawyer should also have a legal duty to warn in the event that a client poses a danger to third parties. Thomas J. Murphy, *Affirmative Duties in Tort Following Tarasoff*, 58 ST. JOHN’S L. REV. 492, 525 (1984). The ABA Model Rules of Professional Conduct permit lawyers to reveal otherwise confidential information “to prevent reasonably certain death or substantial

this are much stronger than reasons against warning in the hypothetical scenarios I sketched in section III.A and the human subjects research context as well. This is because health-care providers owe strong duties of care and confidentiality to their patients. Informing others of the medical conditions or thoughts of patients infringes patient rights to privacy and confidentiality and may have adverse consequences on clinical care; for example, patients may become less inclined to seek out care or disclose information relevant to their care with their providers. In the human subjects research context, the researchers would not be sharing personal information with third parties likely to be affected by it.

Moreover, in the clinical psychology context, informing others of the expressed desires or intentions of clients can put them at risk of non-voluntary institutionalization, for what may or may not be a real intention to harm others. Nevertheless, it seems that a therapist does have a moral duty to warn others in the event she reasonably believes there is a non-trivial risk that her client will harm another person, and that courts were justified in creating a legal duty as well. This is because the therapist is likely in a unique position to prevent serious harm.¹⁴⁴ As other scholars have observed, statutes and judicial decisions compel the disclosure of sensitive health-related information to the affected individual as well as third parties in various other contexts as well.¹⁴⁵

bodily harm." MODEL RULES OF PRO. CONDUCT r. 1.6(b)(1) (AM. BAR ASS'N 2020). Some states have Rules of Professional Conduct *requiring* lawyers to reveal information to prevent certain types of harm to third parties. *See, e.g.*, Ill. Sup. Ct. R. 1.6(c) (2021) ("A lawyer shall reveal information relating to the representation of a client to the extent the lawyer reasonably believes necessary to prevent reasonably certain death or substantial bodily harm.").

144. The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) permits a health care provider to disclose private health information about a patient if the provider believes that the disclosure "[i]s necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public." 45 C.F.R. § 164.512(j)(1)(i)(A) (2020). *See* OFFICE FOR CIVIL RIGHTS, DEPARTMENT OF HEALTH AND HUMAN SERVICES, *FAQ: Does HIPAA Permit a Doctor to Contact a Patient's Family or Law Enforcement if the Doctor Believes that the Patient Might Hurt Herself or Someone Else?* (Sept. 12, 2017), <https://www.hhs.gov/hipaa/for-professionals/faq/2096/does-hipaa-permit-doctor-contact-patients-family-or-law-enforcement-if-doctor-believes-patient.html>.

Likewise, the Privacy Act permits federal agencies to disclose confidential personal records without consent "to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual." 5 U.S.C. § 552a(b)(8) (2018).

145. *See, e.g.*, Benjamin E. Berkman, *Refuting the Right Not to Know*, 19 J. HEALTH CARE L. & POL'Y 1, 41-45 (2016) (discussing Federal Rule of Civil Procedure 35, which permits

A legal duty to return certain individual results in the context of human subjects research would seem consistent with decisions that courts have reached in analogous contexts. As Susan Wolf and coauthors explain, “[i]ncluding among researcher duties an obligation to offer to disclose to participants [findings] that have likely health or reproductive importance is consistent not only with legal recognition of researchers’ special obligations toward participants, but also with legal doctrine imposing a duty to warn of foreseeable harm.”¹⁴⁶ On the other hand, though, there are also reasons to resist any widespread recognition of a legal duty to return results, including potential adverse effects that the threat of liability might have on research.¹⁴⁷ Whether or not the law should compel researchers to inform participants of health-relevant results, it should at the least not prevent or disincentivize disclosure. After all, researchers might be in a unique position to alert participants to significant health risks, as a result of the

courts to “order a party whose mental or physical condition—including blood group—is in controversy to submit to a physical or mental examination by a suitably licensed or certified examiner,” and noting that “examples of compelled genetic testing abound”; and discussing laws requiring pregnant women seeking abortion “to be given specific information about their fetus[es]”); Gitter, *supra* note 111, at 382-83 (discussing state partner notification statutes that “impose[] an affirmative duty on every physician or health care provider authorized to diagnose HIV/AIDS to report the positive status of individuals to the state health commissioner along with the names of any identified spouse, sex partner, or needle-sharing partner . . . so that listed partners may be notified,” but claiming that “[t]he analogy to HIV exposure is not strong enough to justify contacting individuals to tell them directly of their genetic imputed findings absent their informed consent.”).

146. *Managing Incidental Findings*, *supra* note 22, at 229; see also *Law of Incidental Findings*, *supra* note 17, at 366-70 (discussing the *Blaz* case and asserting that “[s]ome recent case law suggests that a legal trend may be emerging toward recognizing an obligation on the part of a researcher to provide a research participant with information acquired from a study, when that information has clinical implications for the participant”); Pike et al., *supra* note 75, at 795 (suggesting that a “possible source of an ethical obligation to return [individual results], is the duty to rescue, which obligates an individual to act when presented with an opportunity to alleviate the serious plight of another with minimal burden to oneself”).

147. See Koch, *supra* note 20, at 210-11 (acknowledging this concern, but also noting that “offering the return of findings to research participants may increase public trust in the research enterprise or even increase general awareness of research protocols, thereby leading to more, rather than less, research participation,” and that “the threat of liability may not have the chilling effect on research that some fear, because the risk of loss of funding or suspension of research is already sufficiently threatening”); see also Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 ANN. INTERN. MED. 40, 40 (2003); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1847 (1996); Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1156 (1987).

researchers' professional expertise and special, perhaps even unique, access to private information. And this is true regardless of whether participants were given the opportunity up front to consent to the return of results.

C. A Right Not to Know?

It would seem somewhat bizarre to insist that, because of a lack of consent to receive information, individuals enjoying their time on the beach should not be informed of environmental risks or that someone in danger of being harmed by a psychologist's patient should not be informed about it. Instead, we generally accept that experts should warn individuals of dangers, even if they have not consented to the warning. The warning seems to be justified because we assume that it is in the recipients' best interests; and the recipients' autonomy is still respected because they can decide for themselves what action, if any, to take in response to the warning. Indeed, our default assumption in these scenarios seems to be that people would want to receive the information, and that they will respond—autonomously, according to their own values and preferences—to it.

Of course, we can imagine how someone in each of the aforementioned scenarios might prefer not to know, how the knowledge might create anxiety, and how, ultimately, it might not help them at all.¹⁴⁸ An individual might have been better off never knowing that they were exposed to some risk.¹⁴⁹ For these reasons,

148. However, research has not uncovered evidence indicating that the receipt of personal genetic information causes significant long-term psychosocial harm. See Berkman, *supra* note 145, at 56–61 (citing studies that found long-term psychological harm of receiving individual results is minimal, and also suggesting that there is little evidence of significant economic harm in the form of genetic discrimination).

149. As Fatehi and Hall, *supra* note 68, at 603–04, assert, commentators and the regulations “express concerns about the devastating psychological harms that a [participant] might face when unexpectedly finding out that they may have a problem,” but minimize “the devastating physical harms that a [participant] might face if they are not informed about a problem they could avoid or mitigate had they been [informed]”: the “potential psychological risks of disclosure are [unjustifiably] elevated over the medical, clinical, and physical risks posed by non-disclosure.” See also Scholtes, *supra* note 35, at 1186 (asserting that “the tangible and intangible costs of not returning incidental findings to participants can be detrimental to society as well as the research enterprise,” and yet most of the literature does not consider these costs); Gitter, *supra* note 111, at 377–78 (drawing attention to the costs of *not* returning individual findings, including the “anguish that may arise when a [past research participant] is diagnosed with a serious medical condition and realizes that it could . . . have been caught and treated earlier,” if individual findings had been returned).

bioethicists often refer to a right on the part of research participants *not to know* about their own health-related risk factors. But if we have no right not to know important health-relevant information in other contexts, it would seem inconsistent to insist nevertheless on a right not to know about individual findings that arise in the context of human subjects research.

Scholars who endorse a right not to know insist that the principle of autonomy requires it.¹⁵⁰ It is unclear, however, why the principle of autonomy should favor a right *not to know* over a right *to know*, or why it would be more paternalistic to return results than withhold them, especially given the empirical evidence suggesting that research participants and prospective participants generally want to receive results and place a high value on them.¹⁵¹

The prevailing insistence on the importance of protecting a right not to know personal information obtained through biomedical research might be described as biomedical exceptionalism: a tendency to afford a special status to biomedical information—or, more specifically, biomedical information derived from biomedical research—without any compelling justification for doing so.¹⁵² Given the empirical evidence

150. See Gitter, *supra* note 111, at 368 (“In the field of biomedical research, the principle of autonomy, or self-determination, suggests that each individual has the right not to know selected information about herself.”).

151. See, e.g., Breitkopf et al., *supra* note 113, at 469, 473 (2015) (finding that, “[c]onsistent with other reports on return of genetic research results, most respondents desired their own results and expected that researchers would extend an offer to learn them”; “[w]hen given a choice between protecting an individual’s right not to know genetic results *versus* offering results to all, fewer than one in five respondents favored the former, even at the risk of upsetting some people by offering results” (emphasis added); and only fourteen percent “agreed with the statement, ‘Researchers should NOT be required to offer genetic results because it’s not their job’”); see also *supra* Section II.C. Other scholars have likewise suggested that withholding individual results based on the belief that the information will harm participants is unjustifiably paternalistic. See, e.g., Conrad Fernandez, *Public Expectations for Return of Results – Time to Stop Being Paternalistic?*, 8 AM. J. BIOETHICS 46, 46–48 (2008) (arguing that, despite the risks associated with returning results, researchers have duties to disclose given participant preferences in favor of disclosure).

152. Many scholars have criticized “genetic exceptionalism,” which is the idea, common among the general public, that personal genetic information is more sensitive and warrants greater protections than other types of personal, health-related information. See Miguel Ruiz-Canela & J. Ignacio Valle-Mansilla, *What Research Participants Want to Know About Genetic Research Results: The Impact of “Genetic Exceptionalism,”* 6 J. EMPIRICAL RES. ON HUM. RES. ETHICS 39, 42 (2011) (finding that people perceive individual genetic data to pose greater risks than other types of health data); Glenn McGee, *Forward: Genetic Exceptionalism*, 11 HARV. J.L. & TECH. 565, 565 (1998) (introducing a journal issue on genetic exceptionalism and explaining that the articles converge around the common theme that “society may not

suggesting that people want to receive results, and given that in other contexts we generally approve of information disclosure even in the absence of consent, the assumption that refraining from disclosing results in biomedical research best protects participant interests and autonomy is untenable.

I do not mean to suggest that results should be forced on people. If a participant expressly declines an offer to receive individual results, then their wish should generally be respected. To defy someone's wishes in that scenario would be extremely intrusive and probably indefensible. Issues of timing and comprehension complicate matters, however, since participants might rotely sign a consent form in advance of a study that indicates they will not receive results, and nevertheless wish to receive a result that arises in the course of research.

In practice, investigators typically do not give participants the opportunity, in advance of the research, to choose whether or not to receive results.¹⁵³ Ideally, participants would be given the chance to opt out, in a reasonably informed way, of receiving results. Even if participants were afforded this chance, however, the empirical evidence strongly suggests that the vast majority would *not* opt out.¹⁵⁴ And so, while perhaps one should ultimately have the right

always benefit from special genetic and reproduction regulations, or special 'exceptions' to existing policies for genetics"). In this Article, I call attention to the broader phenomenon of *biomedical* exceptionalism, which treats personal biomedical information derived from human subjects research as morally distinct from other types of personal information. As far as I know, this form of exceptionalism has not been discussed in the literature.

153. See *supra* Section II.C.

154. No studies, as far as I am aware, have examined how many participants do or would opt out of receiving individual results, but evidence about people's preferences regarding the return of results suggests that opting out would be exceedingly rare. See *supra* Section II.C.

to refuse the receipt of results¹⁵⁵, we should not by default assume that research participants wish to exercise that right.¹⁵⁶

D. Non-Consensual Research

The bulk of the scholarly literature suggests that, whereas researchers have certain duties to return results in the context of consensual research, any such duties may be weaker or nonexistent in the context of non-consensual research (or even broad-consent-based research).¹⁵⁷ This section argues to the contrary that researchers have some strong reasons to return results specifically in the case of research for which informed consent was not obtained.

Many scholars have suggested that the participant's voluntary agreement to participate in the research creates the ethical reasons that weigh in favor of returning results.¹⁵⁸ In my view, however, researchers have compelling ethical reasons to return results even in the absence of voluntary participation. Indeed, the reasons might be even stronger when participation is non-consensual, because the researchers incur a greater debt to participants. When participants

155. See, e.g., Miller et al., *supra* note 48, at 277 (asserting that, “[i]f a subject has explicitly indicated that she does not want to receive incidental findings, this preference should surely be honored”); *Managing Incidental Findings*, *supra* note 22, at 233 (stating that the right of participants “not to know certain categories of information . . . is well-recognized in the genetics literature”); Ebony B. Bookman, Aleisha A. Langehorne, John H. Eckfeldt, Kathleen C. Glass, Gail P. Jarvik, Michael Klag, Greg Koski, Arno Motulsky, Benjamin Wilfond, Teri A. Manolio, Richard R. Fabsitz & Russell V. Luepker, *Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group*, 140 AM. J. MED. GENETICS PART A 1033, 1038 (2006) (stating that “[r]esearch study participants should be given the opportunity [at the consent stage] to decline receiving genetic results and remain eligible for participation if receiving the results is not central to the conduct of the research”); UNESCO General Conference, *International Declaration on Human Genetic Rights*, art. 10 (Oct. 16, 2003), <https://unesdoc.unesco.org/ark:/48223/pf0000133171.page=45> (“[T]he information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results.”); Fernandez, et al., *supra* note 41 (asserting that “[p]articipants have the right to decline receiving all or part of research results”); GRAEME LAURIE, *GENETIC PRIVACY: A CHALLENGE TO MEDICO-LEGAL NORMS* 203–11 (2004) (same); G.A. Res. 53/152, *Universal Declaration on the Human Genome and Human Rights*, art. 5(c) (Dec. 9, 1998), <https://www.ohchr.org/EN/ProfessionalInterest/Pages/HumanGenomeAndHumanRights.aspx> (same).

156. Upon uncovering an individual result, it would be appropriate to ask the affected person whether they wish to receive it before disclosing the finding itself; for reasons I explained above, however, this gesture is unlikely to satisfy proponents of a strong right not to know. See *supra* note 62 and accompanying text.

157. See *supra* Section II.A.1.

158. See *supra* Section II.A.1.

consent to a study, they often receive some kind of remuneration for their participation. Various psychic and emotional benefits are also associated with participating in research.¹⁵⁹ Participants can feel good about contributing to the research enterprise. And they might gain some social capital—respect, gratitude, and admiration—for their participation. Non-consensual participants do not enjoy any of the benefits of willingly contributing to research.

Moreover, willing participants autonomously waive certain rights by consenting to the research—in particular, rights that they would otherwise have to keep their personal biomedical information, such as disease status and DNA, private. Since voluntary participants waive certain privacy rights, researchers do not violate or infringe those rights when they perform tests on biological samples that reveal sensitive, personal information. In the case of research without participant consent, participants do not waive any privacy rights and researchers violate or at least infringe participants' privacy rights in conducting research on their biospecimens and data without consent.¹⁶⁰ Researchers in some sense then owe more to participants who did not consent to the research. By offering to return health-relevant results, the researchers would recognize the unwitting participants' own independent interests, rather than treating them merely as means to realizing research goals. In this way, the researchers can demonstrate respect for participants even if informed consent to the research was not, for whatever reason, obtained.

We can imagine a possible society in which consent for participating in research is not ethically required, but that society is not ours. For example, imagine a society in which it was common

159. See, e.g., Parker, *supra* note 27, at 346 (noting that indirect benefits of participating willingly in biomedical research include “personal satisfaction derived from altruism” as well as “medical testing and care that may be part of the research protocol”).

160. If you have a right to X, and I prevent you from getting X, then I violate your right if and only if it is morally impermissible for me to prevent you from getting X. If I am permitted to prevent you from getting X, which would be true if I have a moral justification for it, then I infringe but do not violate your right. See, e.g., JUDITH JARVIS THOMSON, SELF-DEFENSE AND RIGHTS 9–10 (1976) (discussing the rights violation/infringement distinction). The informed consent requirement in the context of human subjects research is widely accepted in the bioethics literature, and I won't attempt to advance my own argument for it here. The idea, basically, is that researchers may not intervene in an individual's private sphere for research purposes without first obtaining the individual's informed consent to the intervention. See Nir Eyal, *Informed Consent*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Sep. 20, 2011), <http://plato.stanford.edu/archives/fall2012/entries/informed-consent/>.

knowledge that everyone's medical health records and biological samples, even if originally collected for purposes of personal health care, would be reused for undisclosed research purposes. And suppose that research using these materials was regulated such that only studies that are equitable, consistent with public values, and likely to produce public benefit would be permitted. In this kind of society, we would likely see greater public trust in the health care system and in biomedical research than our own, which might help obviate the need for consent to research.¹⁶¹ In the United States today, however, people generally expect to be asked whether they would be willing to participate in biomedical research, and they prefer to be asked—expectations and preferences that are informed by a history of unethical research practices and by the emphasis that bioethicists have put in the past forty years or so on the importance of informed consent in human subjects research.¹⁶² Given this backdrop,

161. See Stephanie A. Kraft, Mildred K. Cho, Katherine Gillespie, Meghan Halley, Nina Varsava, Kelly E. Ormond, Harold S. Luft, Benjamin S. Wilfond & Sandra Soo-Jin Lee, *Beyond Consent: Building Trusting Relationships with Diverse Populations in Precision Medicine Research*, 18 AM. J. OF BIOETHICS 3, 13 (2018) (describing how a history of discrimination against racial and ethnic minorities in the United States has led to distrust in biomedical research and the health care system); Angeliki Kerasidou, *Trust Me, I'm a Researcher!: The Role of Trust in Biomedical Research*, 20 MED., HEALTH CARE & PHIL. 43, 46 (2017) (observing that “[t]he long list of scandals in biomedical research, from the Nazi doctors’ experiments to the more recent cases . . . , it has been argued, has undermined public trust in it” and explaining that “[t]he introduction of laws and rules to regulate biomedical research, and the promotion of transparency and accountability has been seen as . . . a way to reinstate and promote trustworthiness”).

162. See, e.g., Mildred K. Cho, David Magnus, Melissa Constantine, Sandra Soo-Jin Lee, Maureen Kelley, Stephanie Alessi, Diane Korngiebel, Cyan James, Ellen Kuwana, Thomas H. Gallagher, Douglas Diekema, Alexander M. Capron, Steven Joffe & Benjamin S. Wilfond, *Attitudes Toward Risk and Informed Consent for Research on Medical Practices: A Cross-Sectional Survey*, 162 ANNALS OF INTERNAL MED. 690, 694 (2015) (finding that people prefer that researchers ask for their permission before using their medical records in research, and noting that “[their] findings are consistent with other studies that reveal broad support for, and willingness to participate in, research but also a strong desire to be asked for permission before research using medical records, biospecimens, or cluster randomization”); Barbara J. Evans, *In Search of Sound Policy on Nonconsensual Uses of Identifiable Health Data*, in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE 265, 271 (I. Glenn Cohen & Holly Fernandez Lynch eds., 2014) (noting that “[s]urveys reveal that members of the public are troubled by nonconsensual access to their data”); Kraft et al., *supra* note 161 (finding that members of the general public believe that consent is necessary (but not sufficient) for protecting the rights and interests of biomedical research participants); PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, INFORMED CONSENT BACKGROUND (2016), <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/1%20Informed%20Consent%20Background%209.30.16.pdf> (asserting that “[i]nformed consent is not only part of, but is arguably the cornerstone of the conduct of ethical human subjects research,” and

individuals generally have a right to decide whether or not to participate in research.

This is not to say that non-consensual research is never permissible. It may be justified in circumstances where the benefit of the research is likely to be great and the cost of obtaining consent prohibitive. In that event, the researchers would merely infringe, rather than violate, participants' rights by denying them the opportunity to consent to the research. That would not mean, however, that researchers owe nothing to individuals to compensate for the rights infringement. A classic example from the moral philosophy literature helps to illustrate the point:

Suppose that you are on a backpacking trip in the high mountain country when an unanticipated blizzard strikes the area with such ferocity that your life is imperiled. Fortunately, you stumble onto an unoccupied cabin, locked and boarded up for the winter, clearly somebody else's private property. You smash in a window, enter, and huddle in a corner for three days until the storm abates. During this period you help yourself to your unknown benefactor's food supply and burn his wooden furniture in the fireplace to keep warm.¹⁶³

Even though your actions in the blizzard hypothetical are permissible, you have infringed on someone's rights (in this case, property rights), and you owe them some kind of meaningful compensation to make up for the infringement.¹⁶⁴ Likewise, in the case of non-consensual research using individuals' personal health data or biospecimens, even if the lack of consent was permissible, researchers owe something to participants to make up for infringing their rights. If research is consensual, researchers do not owe participants any compensation for infringing their rights, since no rights were infringed. In this sense, non-consensual participants have a greater claim than consensual ones to compensation from researchers.

Henry Richardson, who argues that researchers' duties to return individual results arise from the participant's willing waiver

explaining that informed consent is a central theme of *The Belmont Report*, which the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued in 1978 "to serve as a guide for ethical human subjects research").

163. Joel Feinberg, *Voluntary Euthanasia and the Inalienable Right to Life*, 7 PHIL. & PUB. AFFS. 93, 102 (1978).

164. *Id.*; see also THOMSON, *supra* note 160, at 8.

of privacy rights, presents an analogy to a scenario in which one person permits another to borrow her car. “By accepting the owner’s waiver of” the right to exclusive use of her car, Richardson explains, the borrower takes “on some moral responsibility” to take care of the car.¹⁶⁵ For example, if the car is damaged while in the borrower’s possession, even if through no fault of his own, the borrower has some responsibility to tend to the damage. By emphasizing the role of the car owner’s grant of permission in creating the borrower’s duties of care, Richardson suggests that someone who uses another’s car *without* permission would have lesser or no duties of care with respect to the car. It seems to me, however, that someone who does not get permission subsumes not lesser but *greater* related duties of care.

For example, suppose that I borrow my neighbor’s car in an emergency situation without obtaining her consent. It seems that, in such a case, I would have a stronger moral duty to take care of any damage the car sustained while in my possession than if I had obtained her permission in advance. This is because, if she had granted me permission to use her car, she would have willingly taken on some risk that harm would befall the car while I was using it. And, assuming that I did not assure her I would rectify any damages, she would have assumed some risk that damages would not be repaired. If, however, I borrowed my neighbor’s car without her permission, she has assumed no risk and has no responsibility for anything that happens to the car while in my possession. To make up for my infringement of her property rights, I would owe it to her not only to return the car in the shape I found it, but also to compensate her in some nontrivial way for infringing on her rights. This is analogous to the research setting, in that a researcher who does not obtain the consent of participants has greater moral duties of care and compensation toward them as a result. The analogy illustrates why Richardson and others are mistaken in grounding researchers’ duties of care and compensation in the consent process or the participant’s voluntary participation.¹⁶⁶

165. HENRY S. RICHARDSON, MORAL ENTANGLEMENTS: THE ANCILLARY-CARE OBLIGATIONS OF MEDICAL RESEARCHERS 88 (2012).

166. For a review of literature that grounds duties to return results in consent and voluntary participation, see *supra* Section II.A.1.

E. Expectations

Certain considerations that weigh in favor of the return of results in consensual research scenarios do not apply to non-consensual research. First, participants who consented to a study might expect to receive certain results – perhaps only those related to the primary research questions – and might even rely on that expectation.¹⁶⁷ The potential for expectations and reliance might contribute to researchers' duties to return individual results.¹⁶⁸ For example, if individuals participate in a genetic study and they do *not* receive any results, they might assume that they do not have any genetic risk factors, which might be harmful to them if in fact they do have such risk factors. It is unclear whether and in what research settings consensual participants in fact develop expectations about receiving results, especially if the consent materials are silent on the issue.¹⁶⁹ Regardless, we can be certain that research participants who are not aware of their participation would not expect to receive results. The potential expectations of consensual participants provide an independent reason for researchers to return individual findings in the context of consensual research. The lack of an expectation interest on the part of non-consensual participants, however, does not negate the independent considerations that weigh in favor of returning results to them.

Second, if we consider the universe of consensual research, researchers will have an additional reason to return results to participants in the event that participants were expressly informed in advance that results would be returned. The participants' reasonable expectations of receiving results are highest in this

167. See, e.g., *Managing Incidental Findings*, *supra* note 22, at 228 (suggesting that “researchers’ silence on the topic of clinical problems may be misinterpreted by research participants as a clean bill of health”).

168. See Varsava, *supra* note 49, for a discussion of this point.

169. One study found that sixty-three percent of participants in a cancer biobank and associated family registry “expected to learn something about their own genetic results,” but it is unclear whether the consent form said anything about the return of results. Breitkopf et al., *supra* note 113, at 469 (quoting the study). In a survey study querying previous participants of brain imaging studies about their expectations and preferences regarding the return of incidental findings, fifty-one percent of medical-setting participants and sixty-three percent of non-medical-setting participants “reported that if a brain abnormality existed they would expect it to be detected.” Kirschen, et al., *supra* note 115. The consent forms for the studies that the survey respondents were involved in apparently did *not* indicate that investigators would search for abnormalities but did state that if an abnormality was detected on a participant’s scan, the participant would be informed about it. *Id.*

context, as is the probability that they will rely on those expectations. Moreover, failing to return results in this consent scenario is blameworthy for the reason that it would violate an agreement between researcher and participant – which may count legally as a contract and morally as a promise. If participants were not given the opportunity to consent to the return of results in advance, there would be no such agreement to be broken.

These two considerations show how the reasons weighing in favor of returning results vary somewhat across different consent contexts. But none of this suggests that only those researchers who obtain advanced participant consent to the disclosure of results should disclose them.

F. Costs to Researchers

Despite the reasons that weigh in favor of returning results, in some scenarios the cost of tracking down participants and communicating results to them may be so high that we cannot expect researchers to absorb it.¹⁷⁰ We should keep in mind, though, that the amount of resources available to researchers to run a given study is a function of the budget that the researchers estimate in advance. Currently, researchers have no regulatory reason to budget for the return of results and even have significant reason *not* to budget for this eventuality, given restrictions on planning to return results.¹⁷¹ Indeed the regulations create incentives for researchers to refrain from including plans to return results in their study protocols and so to refrain from requesting grant funding for that purpose. As a result, researchers might find themselves in a situation where they wish to return results but do not have the resources to do so responsibly.¹⁷²

Perhaps funding bodies should take some of the burden upon themselves and earmark funds to support the return of results.

170. As 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) explains, “the practicalities of returning results may impose untenable burdens on the existing research infrastructure”; in large-scale, longitudinal, genome sequencing studies in particular, “[r]eporting back all of the useful results would be extra[ordinarily] costly in time and money.”

171. See *supra* Section II.B.

172. As Scholtes, *supra* note 35, at 1204 asserts, “researchers should address this issue prior to applying for funding.” See also Terry, *supra* note 14, at 734 (noting that “costs for creating and maintaining systems that allow individuals to detail how and when they want results to be reported back to them [could] be built into grants”).

Another possibility, which raises some privacy concerns that would have to be addressed, is that a government agency makes decisions about the return of individual results. Researchers would inform the agency of any health-relevant results uncovered in the course of research, and then the agency would have the responsibility of determining whether the benefits of disclosure justify the costs. The agency could even carry the burden of conveying the results to individuals and covering the associated expenses.

Another possible solution to the cost problem would be to require insurance companies to reimburse the costs associated with the return of results. If receiving results amounts to a type of preventive care, then insurance companies arguably already have duties under the Affordable Care Act to cover the costs.¹⁷³ With the passing of the ACA, many Americans became eligible for expanded coverage of preventive services, with the goal of improving overall health and wellbeing.¹⁷⁴ Access to preventive services may ultimately lower overall health care costs.¹⁷⁵

In any event, I do not mean to argue for an absolute duty to return individual results regardless of costs.¹⁷⁶ Other scholars have proposed frameworks and rules for weighing costs and benefits of

173. This should be taken as a highly tentative suggestion, which would require substantial further research to assess.

174. Patient Protection and Affordable Care Act, 42 U.S.C.S. § 300gg-13 (2018) (providing that “[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for [certain preventive services, including screening]”). For a discussion of the ACA’s preventive medicine provisions, see Amy Burke & Adelle Simmons, *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, ASPE Issue Brief (U.S. Dep’t Health & Hum. Servs.) 1 (June 27, 2014).

175. See Natalia Olchanski, Joshua T. Cohen & Peter J. Neumann, *A Role for Research: An Observation on Preventive Services for Women*, 44 AM. J. PREVENTIVE MED. S12, S15 (2013) (finding that “[t]here is some evidence that better access to preventive services can be maintained at a reasonable cost to the healthcare system, and that certain services may even lower healthcare costs”); Michael V. Maciosek, Ashley B. Coffield, Thomas J. Flottemesch, Nichol M. Edwards & Leif I. Solberg, *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, 29 HEALTH AFFS. 1656, 1660 (2010) (concluding that increased use of preventive medicine is a good use of scarce resources, improves overall health, and is “essentially cost-neutral”).

176. In many situations the cost to researchers of returning individual results may be relatively low. See, e.g., Gordon, *supra* note 35, at 247 (noting that, when it comes to “a finding with a high degree of clinical utility,” “the burdens [of disclosure] are likely to pale in comparison to the benefits,” at least if we assume “that the duty could be discharged by simply informing the subject of the finding”).

disclosing results and determining on that basis when disclosure is ethically advisable; further research along these lines is needed.¹⁷⁷

G. Regulatory Reform

Researchers often do not obtain consent to the return of results in advance of studies. This is a practice that the regulations in various ways encourage. The recommendations in the bioethics literature, however, are largely based on the assumption that researchers will obtain consent to the return of results in advance. In this respect the scope of the ethics literature is limited. This Article argues that researchers will often have strong ethical reasons to return results even in the absence of advanced consent to that effect, and that the law and policy governing human subjects research is misdirected to the extent that it prohibits or disincentivizes researchers from returning results. Policy makers need to make space in the regulations for the appropriate return of results, including in settings where no advanced consent to return was obtained.¹⁷⁸ In this sense, I am arguing for a relaxation of the regulatory requirements. Many details remain to be worked out, however, including just which results warrant disclosure and how the disclosure should be orchestrated.

As we saw above,¹⁷⁹ the issue of returning individual results has mobilized numerous working groups to produce recommendations for investigators who uncover individual results in the course of research. These groups should turn their attention to non-ideal consent settings and develop guidelines for investigators operating in these settings. In particular, we need multidisciplinary groups that include bioethicists; biomedical researchers; geneticists; physicians; and other stakeholders, including research participants themselves, to delimit with more specificity which results qualify as *health-relevant* for the purposes of disclosure. A major challenge is that the health-relevant result is a moving target; more findings will qualify as science and medicine progress, and guidelines will have to be updated accordingly.

177. See, e.g., Scholtes, *supra* note 35.

178. Other scholars have likewise recognized and endeavored “to bring attention to . . . [the] rapidly emerging dissonance between the letter of the federal law and bioethical concerns [including duties to return results]” Fatehi & Hall, *supra* note 68, at 598.

179. See *supra* Section II.A.

In turn, policy makers could incorporate the consensus norms that develop, at least to the modest extent of permitting the return of results whenever the consensus norms recommend disclosure.¹⁸⁰ In this way, the law would incorporate ethical standards in a “gentle” way, making room for optimal ethical conduct without necessarily compelling it. Although law and policy often incorporate consensus standards more aggressively, the context of human subjects research might call for a more gentle incorporation at least for now, given the risks to research that increased legal requirements pose, as well as the dynamic nature of health-relevant results and the inevitable vagueness surrounding the concept.¹⁸¹ Under my proposal—which at this point is preliminary and provisional, with important details remaining to be worked out—researchers would at the least be legally permitted to disclose results whenever disclosure is ethically appropriate. Policy makers

180. The law incorporates extralegal norms in various ways. In the regulatory context, the incorporation is often done “by reference,” meaning that the standards are not directly included in the regulation. See 5 U.S.C. § 552(a) (permitting incorporation by reference); 1 C.F.R. § 51 (2020) (providing instructions for agencies to incorporate standards by reference). See also Nina A. Mendelson, *Public Access to the Law Must Be Taken More Seriously*, REGUL. REV. (Jan. 28, 2015), <https://www.theregreview.org/2015/01/28/mendelson-public-access/> (explaining how “[a]gencies have incorporated—but only by reference—over 9,000 privately drafted standards into binding law”); Emily S. Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J.L. & PUB. POL’Y 131, 134 (2013) [hereinafter Bremer, *Incorporation by Reference*] (“Originally intended to reduce the size and improve the readability of the CFR, incorporation by reference has taken on greater significance as the government has embraced the use of voluntary consensus standards in federal regulations.”). In some contexts, federal law and policy even “require[] agencies to use these privately developed standards instead of creating ‘government unique’ standards solely to serve regulatory purposes.” Emily S. Bremer, *New Rules on Incorporated Standards Encourage Necessary Public-Private Collaboration*, THE REGUL. REV. (Jan. 27, 2015), <https://www.theregreview.org/2015/01/27/bremer-public-private-collab/> [hereinafter Bremer, *New Rules on Incorporated Standards*]. In a different way, the common law also incorporates professional consensus norms. In the medical malpractice context, for example, physicians are held to the standards of the medical profession. This gives rise to legitimate conflicts of interest concerns, however. For this reason, it is important that norm development in human subjects research not be left to researchers alone, who have a self-interest in minimizing financial and administrative costs of research, and that bioethicists and others collaborate with researchers to develop consensus standards. Such consensus standards should be developed through an open and transparent process and should take into account and balance diverse interests. For good reason, these criteria are among the requirements of consensus standards incorporated by reference in regulations. See Bremer, *Incorporation by Reference*, *supra*, at 134. For a critical discussion of the use of practitioner norms in tort standards for professional conduct, see Megan S. Wright, Nina Varsava, Joel Ramirez, Kyle Edwards, Nathan Guevremont, Tamar Ezer & Joseph J. Fins, *Severe Brain Injury, Disability, and the Law: Achieving Justice for a Marginalized Population*, 45 FLA. ST. U. L. REV. 313, 368–70 (2018).

181. For a discussion of these risks to research, see *supra* note 147 and accompanying text.

would not be directly responsible for coming up with provisions concerning just which results ought to be returned and in what manner, and experts and stakeholders would have even more reason to collaborate in the development of careful recommendations concerning the return of results and to disseminate those recommendations broadly.¹⁸²

Some commentators have proposed that research entities “could establish a specialized committee separate from the IRB” to decide which results warrant return; and indeed, some biobanks have done so.¹⁸³ Other commentators recommend that “a national body of scientists can review current genetic knowledge and create uniform standards” regarding which results ought to be disclosed.¹⁸⁴ So far so good. But the guidance literature needs to commit much greater attention to the non-ideal consent context—situations in which participants did not consent to receive results in advance as well as cases of non-consensual research and research based on broad-consent, where participants may not even be aware of their participation in a study. These are not unusual or special circumstances.¹⁸⁵ It is not enough, then, to assume or hope that researchers will obtain consent to the return of results in advance. We have to acknowledge that they do not do so and develop our recommendations concerning the return of results with that reality in mind. Here I have argued that researchers should offer some individual results uncovered in the course of research to participants, even if participants did not consent up front to the disclosure. I have not attempted to determine, however, precisely which results warrant return and what procedures researchers should follow when returning results.

182. The value of this kind of partnership between government agencies and nongovernmental actors is well recognized in the law, policy, and scholarship on the incorporation of standards by reference. *See, e.g.,* Bremer, *New Rules on Incorporated Standards*, *supra* note 180 (observing that this approach to rulemaking “has a variety of benefits and has facilitated a highly valuable public-private partnership in standards-setting”). The idea of incorporating consensus ethical norms into the human subjects research regulations, even in the “gentle” way that I propose, raises some critical questions that are beyond the scope of this Article, including how to ensure adequate participation and notice.

183. Maschke, *supra* note 45, at 569.

184. Matthew J. Piehl, *The Brave New World of Genetic Biobanks: International Lessons for a Potential United States Biobank*, 46 VAL. U. L. REV. 69, 100 (2011).

185. *See supra* Section II.A.

This Article has laid the groundwork for guidance that would address situations in which participants did not consent to the return of results in advance and has shown why such guidance is necessary. The bioethics literature needs to give greater attention to the rights and interests of these participants. The regulations should respond accordingly, making space for the ethical return of results in non-ideal consent scenarios.

CONCLUSION

I have argued that researchers have compelling moral reasons to return results even in contexts where participants did not consent in advance to receive them. This argument fills a gap in the scholarly literature and moreover exposes serious, but remediable, deficiencies in the regulations governing human subjects research and the implementation of those regulations. The law and policy governing human subjects research discourage researchers from returning results to participants and make it especially unlikely that researchers will return results in the event that they did not obtain consent to the return in advance. This represents a major shortcoming in the law and policy landscape.

The Common Rule purports to be grounded in insights from bioethics, and specifically in the fundamental bioethics principles of respect for persons, beneficence, and justice.¹⁸⁶ By allowing for research without informed consent and imposing no requirements on researchers to return results, the regulations facilitate the efficient use of participants in the research enterprise. But insofar as they prohibit or discourage the return of results, the regulations show insufficient respect for the participants on which the research enterprise critically depends.

This Article has addressed some major bioethical and legal questions, but it has also left several collateral questions unanswered. Exactly which results qualify as health-relevant for the purposes of ethical disclosure? And how should researchers disclose such results to participants? Should they perform the disclosure themselves, or delegate the task to a third party? What kind of

186. See The Common Rule preamble, explaining that the regulations seek to serve the ethical principles articulated in the Belmont Report. 45 C.F.R. § 46.101 (2020). For example, “[d]epartment or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.” *Id.* § 46.101(c).

information and guidance should be offered to participants in addition to health-relevant results?¹⁸⁷ These are important questions, but they will have to await future research, and are best addressed by multidisciplinary groups comprised of legal scholars, bioethicists, biomedical researchers, geneticists, physicians, and research participants themselves.

Scholars addressing duties to return results have often presupposed an ideal consent setting, and have neglected difficult but pressing questions about how researchers should handle individual results when consent is lacking or otherwise deficient. The existing related literature thus does not sufficiently attend to the rights and interests of participants who did not consent up front to the return of results. The regulations do not help matters. In multiple ways, they discourage researchers from disclosing results if participants were not given the opportunity up front to consent to the disclosure. The rules thus disserve a critical group of research participants. This Article contributes to the law, policy, and ethics literature by addressing researcher responsibilities to return results in non-ideal consent settings; by illuminating related limitations with the regulations, which create obstacles to disclosing results to participants even when researchers may have moral obligations to do so; and by proposing a provisional path to remedy the problem presented.

The law should not prohibit or discourage investigators from returning individual health-relevant findings to those affected by them—certainly not in public health emergencies such as the outbreak of COVID-19 in the United States, but not under normal circumstances either. The COVID-19 example shows just how high and urgent the stakes can be. But we should treat it as a lesson in the

187. See, e.g., Gordon, *supra* note 35, at 230 (observing that, “because genetic information is seen as weightier and harder to understand [than other types of health information], disclosure without accompanying genetic counseling is widely considered ethically problematic”); Renegar et al., *supra* note 41, at 34 (recommending that those “responsible for communicating the genetic results to participants should” be knowledgeable about “the genetic science associated with the study . . . [a]ppreciate the potential social and psychological impact on the individual . . . [c]ommunicate . . . about the study results effectively[,]” and “[k]now when and how to refer participants for additional care and/or information”); see also RICHARDSON, *supra* note 165 (arguing that researchers have duties not only to return results in certain contexts but also to provide some related, or “ancillary,” care).

value of disclosing results and not as an exception to an otherwise desirable rule against disclosure in the absence of consent.

