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Susanna McGrew

Sarah Raskoff

Benjamin E. Berkman

WHEN NOT TO ASK: A DEFENSE OF CHOICE-MASKING NUDGES IN MEDICAL RESEARCH

SUSANNA MCGREW*, SARAH RASKOFF**, AND BENJAMIN E. BERKMAN***

ABSTRACT

In this article, we examine the legality and ethics of a controversial but widespread practice in clinical research: choice-masking nudges. A choice-masking nudge (CMN) exists when a research team explicitly obscures a meaningful choice from participants by presenting a default decision as the standard way forward. Even though an easy-to-use opt-out mechanism is available for participants who independently express concerns with the standard default, the fact that a default has been pre-selected is not made obvious to research participants. To opt out of the nudge, a participant must overtly request non-standard treatment. We argue that use of such nudges in medical research can be justified by their individual, collective, and social benefits, provided that they respect autonomy and satisfy four additional acceptability conditions. In Part II of this Article, we describe three controversial cases of CMNs in medical research. In Part III, we provide background on nudging and explain how our proposed CMNs fit into the existing literature on nudging and libertarian paternalism. In Part IV, we explain how the reasonable person standard as employed by United States research regulations can be used to support CMNs. In Part V, we anticipate some of the strongest objections to CMNs by explaining

* Susanna McGrew is a postbaccalaureate fellow in the Department of Bioethics at the National Institutes of Health.

** Sarah Raskoff, PhD, is a postdoctoral fellow in the Department of Bioethics at the National Institutes of Health.

*** Benjamin E. Berkman, JD, MPH, is a faculty member in the Department of Bioethics at the National Institutes of Health, where he is the head of the section on the ethics of genetics and emerging technologies. He has a joint appointment as an Associate Investigator in the National Human Genome Research Institute, where he also serves as the Deputy Director of the NHGRI Bioethics Core. The views herein are the authors' and do not represent the views or policies of the Department of Health and Human Services or the National Institutes of Health. This research was supported in part by the National Institutes of Health Clinical Center and the Intramural Research Program of the National Human Genome Research Institute. The authors have no financial, personal, academic, or other conflicts of interest in the subject matter discussed. The authors would like to thank Joe Millum, Holly Taylor, Leila Jamal, David Wendler, and Sarah Royka for comments that improved the manuscript.

how CMNs are compatible with a wide range of plausible accounts of autonomy. Finally, in Part VI, we discuss four additional core considerations an acceptable CMN must meet: legitimate policy goals; benefits outweighing harms; burdens distributed fairly; and absence of ethically superior feasible alternatives. We also revisit and analyze the three existing controversies previously explored in Part II and show how each would benefit from the conceptual clarity offered by our analytic framework. Medical research is complicated and can be difficult for participants to understand. Thoughtfully designed CMNs can play an important role in gently guiding large numbers of research participants toward decision outcomes that really are best for them and their communities.

I. INTRODUCTION

This paper focuses specifically on nudging participants in medical research. Nudges are ubiquitous; they come from our smartphones and our employers,[1] regarding things as different as food choice[2] and energy consumption.[3] Regardless of the source, however, *all* nudges attempt to influence nudgees' choices by changing the way options are presented.[4] Although nudging is all around us and even permeates medical care,[5] its use in medical research prompts unique ethical and regulatory concerns. For instance, beyond the way researchers present information about costs and benefits, may they go so far as to implement default choices that participants would have to actively opt-out of to avoid? More concretely, may we nudge participants towards receiving medically actionable information they might not ask for? May we nudge new parents towards contributing their newborn infant's blood spot for future research use? May we nudge participants to deposit their research data in repositories where other investigators can access them to help answer a broad range of secondary scientific questions? We argue that as long as certain acceptability considerations are satisfied, nudges that mask choices regarding those questions *can* be ethically and legally acceptable.

A choice-masking nudge (CMN) is a particular kind of nudge that exists in medical research when a research team explicitly obscures a meaningful choice from participants by presenting a default decision as the standard way forward. Even though an easy-to-use opt-out mechanism is available for participants who independently express concerns with the standard default, the fact that a default has been pre-selected is not made obvious to research participants. Consider, for example, a consent form stating that secondary genetic findings may be returned to research participants (and explaining what that means) without providing the participant with an opportunity to explicitly consent.[6] In that case, the form does not advertise the fact that receiving secondary findings has been deliberately pre-selected. To opt out of the nudge, a participant would need to *ask* the researchers to receive non-standard treatment—in this case, to not receive any secondary genetic findings. Since all CMNs must give nudgees a fair chance of opting out,

1. *See, e.g.,* RICHARD THALER & CASS SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS 109 (2008) (showing that automatic enrollment is a nudge that employers can use to increase employee participation in employer sponsored retirement plans).

2. *Id.* at 2.

3. *See, e.g.,* Hunt Allcott & Todd Rogers, *The Short-Run and Long-Run Effects of Behavioral Interventions: Experimental Evidence from Energy Conservation* 104 AM. ECON. REV. 3003 (2014) (showing how consumers respond to home energy reports designed to reduce energy use when these reports are repeatedly mailed to their home).

4. THALER & SUNSTEIN, supra note 1, at 6.

5. *See, e.g.,* Bart Engelen, *Ethical Criteria for Health-Promoting Nudges: A Case-by-Case Analysis*, 19 AM. J. BIOETHICS 48, 48 (2019) (discussing nudging in clinical care).

6. *See infra* Part II.A (providing an overview on the debate over return of genetic results).

nudgees should be made aware (at least in general terms) that some options may have been pre-selected as defaults and that they may choose to select a different option. Consent forms could include a disclaimer suggesting that participants who think they might prefer a different treatment than the one indicated should raise any concerns with the research team (for example, "please ask a member of the research team if you have any questions or concerns about automatic return of secondary findings"). This kind of general disclaimer is not expected to significantly reduce the efficacy of the CMNs; on the contrary, research in other contexts has shown that informing individuals that they are being nudged does not tend to reduce the nudge's effectiveness.[7]

There are four elements of CMNs that are worth emphasizing. First, researchers are prohibited from masking information regarding the default choice.[8] Researchers avoid masking such information when the issue in question and the default action are clearly described, but the *choice* regarding the default action is masked by not presenting an opportunity to make an explicit choice.[9] Second, because CMNs are not binding, participation in research does not depend on agreeing to the default action.[10] Third, the CMN must be easy to resist.[11] That means that the opt-out mechanism to pursue an alternative to the default action must be easy to use after the participant self-identifies a concern.[12] And fourth, CMNs must include meaningful choices—either because they are likely to have non-trivial impact, or because a sizable number of participants are expected to have strong preferences about them (in contrast to the mundane choices that are routinely hidden from research participants, such as the method of contact with the research team). Ideally, CMNs will have the greatest effect on research participants who do not have strong prior preferences about the choice that is masked, since those who do have strong preferences are more likely to notice and opt out of the nudge.[13] While we offer a variety of relevant considerations for analyzing the ethical acceptability of a CMN within a broad,

7. *See* George Loewenstein et al., *Warning: You Are about to be Nudged,* 1 BEHAV. SCI. & POL'Y 35, 36 (2015) (comparing nudges to the more forceful alternative of authorized deception in medical research); *see also* Frank Miller et al., *Deception in Research on the Placebo Effect,* 2 PLOS MED. 853, 854 (2005) (comparing double blind placebo tests to investigations where the investigator intentionally withholds information from the participant).

8. *See infra* Part IV.C.

9. *See infra* Part IV.C.

10. *See infra* Part III.

11. *See infra* Part III.

12. *See infra* Part III.

13. *See infra* Part IV. In practice, nudges are likely to have a strong impact on individuals who have low literacy, feel highly deferential to medical expertise, or more generally feel unempowered in the medical system, even if they have strong preferences. *See infra* Part IV. As we discuss later, researchers should take those consideration into consideration when designing nudges and attempt to mitigate their effects. *See infra* Part IV.

flexible framework, this paper does not provide an algorithmic account of how these various considerations weigh against each other in every circumstance.

The following examples of CMNs are all controversial and likely to meet serious opposition, stemming from a few ethical concerns. First, the perceived primacy of autonomy in the bioethics literature may lead critics to claim that our analysis of CMNs gives short shrift to that principle, particularly regarding the autonomy interests of individuals who would prefer not to be nudged. Bioethicists commonly identify four primary moral principles: autonomy, nonmaleficence, beneficence, and justice.[14] Autonomy, however, is often treated as first among equals, and any perceived infringement of a research participant's autonomy is taken very seriously.[15] In this paper, we push back against the idea that autonomy should be the foremost ethical concern when analyzing the appropriateness of CMNs. While autonomy is relevant and constrains the scope of acceptable CMNs, considerations of individual, collective, and societal benefit are also crucial to our ethical analyses (and may not always align with maximally promoting autonomy).

Second is the related issue of dealing with the tail of the curve. In most research cohorts, there will be a small group of participants who have outlier views or preferences.[16] Respecting these differences to help this small group make more informed decisions could impact the larger research cohort, or even the research enterprise as a whole. In cases where nudges cannot be feasibly tailored to individuals, heterogeneity among participants makes it unlikely that all nudgees will benefit from or even be equally affected by the nudge.

Third, regulatory opposition will likely come from the perception that CMNs cut against the large body of jurisprudence that emphasizes informed consent in medical research. However, while the Federal Policy for the Protection of Human Subjects (the revised Common Rule) explicitly mandates disclosure of relevant information and an opportunity to discuss it, it does not mention active solicitation of preferences.[17] Instead, our justification for CMNs

14. TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 13 (8th ed., 2019).

15. *See* Raanan Gillon, *Ethics Needs Principles—Four Can Encompass the Rest—and Respect for Autonomy Should Be "First Among Equals,"* 29 J. MED. ETHICS 307, 307 (2003) (arguing that autonomy should be the first principle among ethical principles because autonomy is contained within the other three principles); CHARLES FOSTER, CHOOSING LIFE, CHOOSING DEATH: THE TYRANNY OF AUTONOMY IN MEDICAL ETHICS AND LAW (2009).

16. Ceyda Özhan Çaparlar & Aslı Dönmez, *What is Scientific Research and How Can it be Done?*, 44 TURKISH J. OF ANAESTHESIOL REANIMATION 212, 216 (2016).

17. 45 C.F.R §46.116 (a)(4) (2019) ("The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."); *Cf.* SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS, GUIDANCE ON BROAD CONSENT UNDER THE REVISED COMMON RULE 12 (2017) (explaining that official guidance on broad consent under the revised Common Rule allows research participants to authorize unspecified future uses

invokes the reasonable person standard, which has often been *interpreted* to require preference solicitation.[18]

In this paper, we draw a distinction between nudges with implications for information use (informational nudges) and nudges with direct physical implications (physical nudges). The former concerns actions regarding the treatment of information gained from research, while the latter have to do directly with physical procedures that have significant implications for bodily integrity.[19] Thus, a nudge concerning drawing a blood sample for clinical care would be physical, while a nudge concerning what is to be done with what remains of the leftover sample would be informational. We claim that it is reasonable to not explicitly solicit consent for aspects of research with predominantly informational implications, provided that there is sufficient information disclosure, that our other acceptability considerations are met, and that doing so is consistent with current United States research regulations.

The remainder of this Article is organized as follows. In Part II, we present three cases of medical research decisions where CMNs could be implemented. In Part III, we provide background on nudging and explain how our proposed choice-masking nudges fit into the large existing literature on nudging and libertarian paternalism.[20] In Part IV, we explain how the reasonable person standard as employed by United States research regulations can be used to support CMNs.[21] In Part V, we anticipate some of the strongest objections to CMNs by discussing prominent features of various views of autonomy, and explaining how CMNs are compatible with a wide range of plausible accounts of autonomy.[22] Finally, in Part VI, we lay out four core considerations relevant to the acceptability of CMNs: legitimate policy goals; benefits outweighing harms; burdens distributed fairly; and absence of ethically superior feasible alternatives.[23] We also revisit and analyze the three cases presented in Part II, in light of those considerations. A CMN that respects autonomy and that satisfies the considerations relevant to acceptability, we argue, can plausibly be justified on the basis of individual, collective, or social benefit.[24]

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of their research data without preference solicitation about each one). Our focus here is on the text of the revised Common Rule, which appears to pose a greater legal challenge to CMNs than the more permissive guidance. Attachment C to Letter from Stephen Rosenfield, Secr'y's Advisory Comm. on Hum. Rsch. Protections Chair, to Thomas Price, Sec'y of Health and Hum. Serv. (Aug. 2, 2017) (available at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html).

18. *See infra* Part III.A.

19. *See supra* notes 74–75 and accompanying text. Even informational nudges may have downstream physical consequences, such as information about genetic risks leading someone to seek preventative care. *Id.* But that level of interaction between the informational and physical does diminish the intuitive distinction between nudges that are primarily informational and primarily physical. *Id.*

20. *See infra* Part III.

21. *See infra* Part IV.

22. *See infra* Part V.

23. *See infra* Part VI.

24. *See infra* Part VII.

II. THREE CASES OF CHOICE-MASKING NUDGES IN RESEARCH

A. The Right Not to Know Genetic Information About Oneself

In the past fifteen years, advances in genomic sequencing technology have given us the capacity to rapidly and inexpensively sequence a person's entire genome.[25] Physicians and researchers quickly began incorporating this powerful tool into their arsenal.[26] While next-generation sequencing has radically changed how science is conducted, researchers and Institutional Review Boards (IRBs) have struggled with the ethical implications of this new technology.[27] In particular, given that massive amounts of data generated by genomic sequencing can contain clinically actionable findings unrelated to the specific condition being investigated, the research community has vigorously debated about whether and how to honor participants' so-called right not to know (RNTK) genetic information about themselves.[28]

For illustration, imagine IRB deliberations regarding whether to ask participants if they want to learn about any heightened cancer susceptibility that their sequence data could reveal. There are two options, both of which involve accepting that a mistake will be made. If an IRB requires investigators to actively solicit preferences, it is almost certain that some people will choose not to receive

25. *See* Eric D. Green, *Strategic Vision for Improving Human Health at the Forefront of Genomics*, 586 NATURE 683, 683 (2020) (explaining the significant advances made in the development of human genome sequencing technology); *see also,* Nat'l Hum. Genome Rsch. Inst.*, The Cost of Sequencing a Human Genome*, GENOME.GOV (July 26, 2020), https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost (demonstrating that the cost of sequencing a genome has dropped from over $10 million to less than $1,000 over the past two decades).

26. Teri A. Manolio et al., *Opportunities, Resources, and Techniques for Implementing Genomics in Clinical Care*, 394 LANCET 511, 511 (2019).

27. *See, e.g.*, Amy L. McGuire et al., *Research Ethics and the Challenges of Whole Genome Sequencing*, 9 NATURE REV. GENETICS 152, 152 (2008) (describing the major ethical considerations raised by new genomic sequencing technologies).

28. Benjamin E. Berkman, *Refuting the Right Not to Know*, 19 J. HEALTH. CARE L. POL'Y 1, 6 (2017). Early in the adoption of genetic testing (circa 2000), there was substantial debate about a patient's right not to know genetic information about themselves. *Id*. at 9. A few scholars took an absolutist position, arguing that the right not to know information about oneself was sacrosanct. *See, e.g.*, Roberto Andorno, T*he Right Not to Know: An Autonomy Based Approach*, 30 J. MED ETHICS 435, 436–37 (2004) (arguing that the right not to know is based in psychological spatial privacy which safeguards one's sense of self). Other scholars saw freedom from unwanted genetic information as an important, but defeasible right that needed to be balanced against other considerations. *See, e.g.,* Graeme Laurie, *Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications*, 42 J. MED. ETHICS 53, 58–59 (2014) (arguing that the right to refuse genetic information must be balanced with public health concerns, economic costs, and the public health burdens that one's disease may impose if information is withheld for the sake of preserving autonomy); Jonathan Herring & Charles Foster, *"Please Don't Tell Me"*, 21 CAMBRIDGE Q. HEALTHCARE ETHICS 20 (2012). Other scholars took an even more skeptical view of the RNTK, arguing that blinding oneself to important information actually restricts autonomy. *See, e.g.*, Rosamond Rhodes, *Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge*, 23 J. MED. AND PHIL. 11, 15–18 (1998). This initial debate was limited, however, by the relatively narrow scope of the nascent genetic medicine field. *Id*.

their cancer predisposition information without fully understanding the implications of this choice. Perhaps subjects will make this choice because they do not understand the nature of the information they are refusing and/or because they fear the anxiety associated with confronting bad news. Whatever the reason, soliciting preferences means accepting that some people will not gain access to potentially life-saving treatment that they would have actually wanted had they been fully informed.[29] In contrast, if investigators do not actively solicit preferences, some people could be forced to confront the fact that they might battle cancer in the future, even though they would have legitimately preferred not to know this fact.[30]

Rightly sensing a need for professional ethical guidance, the American College of Medical Genetics and Genomics (ACMG) published recommendations suggesting that there is an obligation to look for secondary findings, and that those findings be routinely returned without soliciting a patient's preference for knowing or not knowing that information.[31] These recommendations sparked an extended heated debate about the importance of the RNTK,[32] eventually prompting the ACMG to revise their guidance to specify that patients must be given an opportunity to opt-out of receiving genetic information.[33] This RNTK debate was particularly heated in the research context, where open questions about the scope of an investigator's clinical responsibilities towards their research subjects persist.

B. Newborn Blood Spot Research

A day or so after birth, a nurse will approach new parents about obtaining a tiny blood sample (typically from a heel stick) that can screen their newborn

29. *See* Will Schupmann et al., *Exploring the Motivations of Research Participants Who Choose Not to Learn Medically Actionable Secondary Genetic Findings about Themselves,* GENETICS IN MED. 1, 3 (2021) (demonstrating that about half of initial refusers change their minds ("reversible refusers") while the other half maintain their initial decision not to know ("persistent refusers")).

30. *Id.* at 4.

31. Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETIC MED. 566, 568 (2013). Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETIC MED. 565 (2013).

32. *See* Berkman, *supra* note 28, at 12–21 (summarizing the heated debate about the RNTK prompted by the ACMG recommendations); Meredith Waldman, *Controversy Flares Over Informing Research Subjects about 'Incidental' Genetic Findings*, SCIENCE (Aug. 2, 2021, 4:45PM), https://www.science.org/content/article/controversy-flares-over-informing-research-subjects-about-incidental-genetic-findings (showing that the heated dispute over the need to ask participants about the RNTK remains active and unresolved).

33. AM. COLL. OF MED. GENETICS AND GENOMICS, *ACMG Policy Statement: Updated Recommendations Regarding Analysis and Reporting of Secondary Findings in Clinical Genome-scale Sequencing*, 17 GENETIC MED. 68, 68 (2015).

infant for a range of conditions that generally require early intervention.[34] While newborn screening is an important public health activity, the samples can also be extremely valuable from a medical research standpoint.[35] Since these newborn bloodspots (NBS) are taken from almost all newborns, they provide an opportunity to generate population-level data about public health questions and can be vital for ascertaining rare disease cases in sufficient numbers to conduct rigorous research.[36] NBSs are also uniquely useful in epidemiological research, particularly relating to infectious diseases and environmental exposures.[37] Traditionally, because these bloodspots are deidentified, research activities were not considered to be human subjects research under the Common Rule.[38] Thus, researchers have generally been allowed access to the samples without explicit informed consent. In the hours before being discharged from the hospital, new parents are generally given a brochure (along with a stack of other forms and pamphlets) that explains how the NBS research program works and provides information about the mechanism parents can use to opt-out.[39] One can reasonably question whether new parents have the cognitive capacity to fully engage with this kind of abstract question, buried in an avalanche of other more urgently important information, in the disorienting few days after delivery.

It is not surprising then that scholars and advocates have raised multiple concerns about the research use of NBS samples even though they hold significant scientific value. The primary argument is that it is unethical (and deceptive) to store samples for future research use without first having obtained explicit consent to do so.[40] There are concerns about tangible harms flowing from the use of these samples[41] and about non-welfare harms (such as using samples

34. *See* Michelle H. Lewis et al., *State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples*, 127 PEDIATRICS 703, 706–707 (2011) (demonstrating that most states do not require prenatal disclosure of information about research uses of newborn blood spots).

35. STEVE OLSON & ADAM C. BERGER, INST. OF MED., CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH 9–15 (The Nat'l Academies Press, 2010).

36. Michelle J. Bayefsky et al., *Parental Consent for the Use of Residual Newborn Screening Bloodspots: Respecting Individual Liberty vs Ensuring Public Healt*h, 314 JAMA 21, 22 (2015).

37. Jeffrey R. Botkin et al., *Retention and Research Use of Residual Newborn Screening Bloodspots*, 131 PEDIATRICS 120, 121 (2013) [hereinafter *Botkin I*].

38. Marianna J. Bledsoe & William E. Grizzle, *Use of human specimens in research: the evolving United States regulatory, policy, and scientific landscape*, 19 DIAGNOSTIC HISTOPATHOLOGY 322, 335–36 (2013).

39. *See* Jeffrey R. Botkin et al., *Prenatal Education of Parents about Newborn Screening and Residual Dried Blood Spots*, 170 JAMA PEDIATRICS 543, 544 (2016) [hereinafter *Botkin II*] (arguing that "the hectic postpartum environment and the need to address other health care priorities in newborn and maternal care contribute to the poor efficacy for current educational approaches").

40. Jennifer Couzin-Frankel, *Science Gold Mine, Ethical Minefield*, 324 SCIENCE, April 10, 2009, at 166.

41. OLSON & BERGER, *supra* note 35, at 19–29.

to conduct controversial research that the source of the sample would not want to support).[42] These concerns have led to a number of high-profile court cases, where parents have successfully challenged NBS research programs that do not actively solicit consent.[43]

The desire to obtain consent is understandable, but researchers have voiced concerns that imposing such a requirement would reduce participation rates, thus undermining the value of a resource as a broad representation of the population.[44] This has led professional societies and policymakers to issue a range of guidance positions. The American Society of Human Genetics (ASHG), in a 2015 update of their guidance on pediatric genetic testing, advocated for parents to be given a choice about future research use of NBS samples.[45] Even more radically, the ACMG and the American Academy of Pediatrics (AAP) jointly argued for the necessity of consent before any newborn screening (let alone research) is conducted. The AAP did, however, remain flexible about the form that the consent process can take.[46] Other groups remain equivocal,[47] argue in favor of the status quo,[48] or endorse the acceptability of an opt-out approach.[49]

42. Raymond D. De Vries et al., *The Moral Concerns of Biobank Donors: The Effect of Non-welfare Interests on Willingness to Donate*, 12 LIFE SCI. SOC'Y & POL'Y 1, 2 (2016).

43. *See* Beleno v. Tex. Dep't of State Health Servs., No. SA-09-CA-0188-FB, 2009 WL 5072239 (W.D. Tex. Sept. 29, 2009); Bearder v. State, 806 N.W.2d 766, 776 (Minn. 2011). In *Beleno*, after winning a preliminary motion on the question of whether the research might plausibly violate 14th Amendment privacy rights, the parties settled out-of-court, resulting in destruction of 5.3 million samples that had been stored for future research. Beleno, No. SA-09-CA-0188-FB, 2009 WL 5072239. *Bearder* went to the state supreme court, which found that the genetic information contained in the samples meant that certain state laws applied that created safeguards related to the retention and use of genetic information. 806 N.W.2d. As a result, Minnesota destroyed all samples collected before 2011. Bayefsky et al., *supra* note 36.

44. Erin Rothwell et al., *Secondary Research Uses of Residual Newborn Screening Dried Bloodspots: A Scoping Review*, 21 GENETIC MED. 1469, 1470 (2019).

45. Jeffrey R. Botkin et al., *Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 97 AM J. HUM. GENETICS 6, 8 (2015) [hereinafter *Botkin III*].

46. Laine Friedman Ross et al., *Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children*, 15 GENETIC MED. 234, 236 (2013).

47. AM. COLL. OF OBSTETRICS AND GYNECOLOGY, AC*OG Committee Opinion No. 778 Summary: Newborn Screening and the Role of the Obstetrician-Gynecologist*, 133 OBSTET. GYNECOL. 1073 (2019).

48. SEC'Y ADVISORY COMM. ON HUM. RSCH. PROTECTIONS*, Attachment E: Recommendations Regarding Research Uses of Newborn Dried Bloodspots and the Newborn Screening Saves Lives Reauthorization Act of 2014*, DEP'T OF HEALTH AND HUM. SERVS. (April 24, 2015), https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-april-24-attachment-e/index.html.

49. *Botkin II*, supra note 39, at 122–23.

C. GENOMIC DATA SHARING

In 2015, the National Institutes of Health (NIH) implemented a genomic data sharing policy that applied to all NIH-funded research.[50] Any project that would generate large-scale genomic data was expected to deposit their data in a public repository that could be accessed by other researchers.[51] The purpose of the NIH genomic data sharing (GDS) policy was to increase the amount of available genomic data, which in turn allows for more powerful analyses of the relationships between genetics and human health.[52] NIH has a long history of encouraging the sharing of data, but the GDS represented an ambitious attempt to move towards the promise of personalized medicine.[53] Since most genetic traits are not mendelian, aggregation of large genomic data sets allows for researchers to explore the complex relationships between an array of interrelated genetic variants that can each contribute in subtle ways to a given health trait or disease.[54]

With the advent of this policy, there has been extensive literature on balancing the maximization of data utility with the protection of human subjects from the risks of broad genomic data sharing.[55] If explicit consent is required, some people will decline to share, thus decreasing the breadth and value of the data.[56] Though there have been calls for tiered consent[57] (where subjects are given choices about how their data can be shared), there is also a recognition that

50. *NIH issues finalized policy on genomic data sharing*, NAT'L INSTS. OF HEALTH (Aug. 27, 2014), https://www.nih.gov/news-events/news-releases/nih-issues-finalized-policy-genomic-data-sharing.

51. *Id.*

52. *Id.*

53. NAT'L INSTS. OF HEALTH, PREAMBLE FOR THE GENOMIC DATA SHARING POLICY 1 (2014).

54. James Brian Byrd et al., *Responsible, Practical Genomic Data Sharing that Accelerates Research*, 21 NATURE REV. GENETICS 615, 616 (2020).

55. *See, e.g.*, Luca Bonomi, Yingxiang Huang & Lucila Ohno-Machado, *Privacy Challenges and Research Opportunities for Genomic Data Sharing,* 52 NATURE GENETICS 646, 649–50 (2020) (noting that broad consent can increase the utility of genomic data as it allows for individuals to give consent for their primary research information for general research in the future); *see also* Linus Johnsson, *Hypothetical and Factual Willingness to Participate in Biobank Research*, 18 EUR. J. HUM. GENETICS 1261, 1261 (2010) (finding that for biobank research to be successful, people must view it positively because regulation practices use people's attitudes in survey assessments).

56. *NIH Genomic Data Sharing Policy*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html (last visited Dec. 10, 2021).

57. *See* Amy L. McGuire et al., *To Share or Not to Share: A Randomized Trial of Consent for Data Sharing in Genomic Research*, 13 GENETICS MED. 948, 954 (2012) (finding that tiered consent gives participants options ethically, but does not seriously hamper research); Amy L. McGuire et al., *DNA Data Sharing: Research Participants' Perspectives*, 10 GENETICS MED. 46, 47 (2008) ("We have advocated for tiered consent, which does not compromise research participation and affords individuals the most control and flexibility with regard to their genetic data sharing and release options . . .").

it is sometimes acceptable to maximize the deposition of genomic data by not presenting an explicit choice about sharing one's data.[58]

Unlike the NBS consent debate, policy guidance related to implementation of the GDS policy called for explicit consent and rejected opt-out systems.[59] Even if a decision was made that CMNs were not appropriate when obtaining consent for broad sharing of genomic data, the debate about the contours of what is or is not ethically appropriate are relevant to our discussion. Policy makers attempted to navigate between the competing requirements of what law, ethics and public opinion required, while not unnecessarily limiting the scope of data sharing.[60]

Though the GDS policy outlines an expectation that explicit consent will be obtained, this tension is illustrated by the NIH Office of Science Policy's (OSP) suggestion that a number of consent features that leave open the possibility that explicit consent for the broad sharing of genomic data will not be necessary in some situations. For example, though explicit consent would be necessary for open access, OSP guidance suggests that explicit consent is not necessary for data to be deposited in the controlled access tier.[61] Similarly, when the original research project has been granted a waiver of informed consent or when the Common Rule regulations do not apply, mere disclosure of the data sharing plan may be sufficient and exceptions to the consent requirement can be sought.[62]

In practice, it appears that research institutions have favored broad consent strategies.[63] One can imagine a range of possible consent approaches, from very granular to very passive.[64] On the granular end, research subjects could be presented with a detailed series of choices about how their data can be used (such as a tiered consent).[65] A less granular, but still explicit approach, includes

58. Jill M. Oliver et al., *Balancing the Risks and Benefits of Genomic Data Sharing: Genomic Research Participants' Perspectives,* 15 PUB. HEALTH GENOMICS 106, 113 (2012) ("However, in studies where the primary goal is to create a community resource (e.g., a biobank), data sharing may be a condition of participation and so tiered consent would not be practical or easy to implement.").

59. *Genomic Data Sharing*, NAT'L INST. OF HEALTH OFF. OF SCI. POL'Y, https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/ (last visited Oct. 10, 2021).

60. *See id.* (noting that not only does the NIH have committees that inform the director of scientific and ethical updates, but it also conducts periodic reviews of its research policies).

61. NAT'L INST. OF HEALTH, NIH GUIDANCE ON CONSENT FOR FUTURE RESEARCH USE AND BROAD SHARING OF HUMAN GENOMIC AND PHENOTYPIC DATA SUBJECT TO THE NIH GENOMIC DATA SHARING POLICY (NOV. 1, 2018), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf.

62. *Id*. ("At minimum, the information described above should be provided to prospective participants. Investigators may request exceptions to the NIH consent expectations for compelling scientific reasons.").

63. Zubin Master et al., *Biobanks, Consent and Claims of Consensus*, 9 NATURE METHODS 885, 885–86 (2012).

64. *See id.* (discussing different consent types).

65. *Id.*

providing details about the data sharing plan and giving an explicit choice about whether to opt-in.[66] A more passive approach includes asking for broad consent by including details about the data sharing plan in the consent process without drawing special attention to it or asking for consent about that discrete topic; general consent to participate would include agreement to broad data sharing.[67] According to one review of consent materials, granular, tiered consent appears uncommon, with the majority of research institutions obtaining one-time broad consent as part of the standard consent process (which does not include obtaining separate, explicit consent for data sharing).[68] The concept of asking for high-level rather than granular consent is therefore in line with the spirit of CMNs.

Though none of these debates were framed in terms of nudging, they all raise questions about the propriety of instituting an institution-level choice masking nudge. Is it ethically acceptable to nudge research participants towards receiving genetic information by hiding the existence of an opportunity to opt out of learning such information? Similarly, is it ethically acceptable to hide a choice to opt out of having your infant's sample be stored for later research use, creating a default that maximizes the number of available research samples? And is it acceptable to require only broad consent in research, instead of requiring that participants agree to more granular options? Questions of this variety abound in medical research, and as the GDS case shows,[69] the text of regulations alone does not always clarify what should be done in practice. For that reason, we provide commentary on the applicability of the reasonable person standard, the legal standard applied to informed consent regulations to supplement our reading of the regulations.

III. LIBERTARIAN PATERNALISM AND CHOICE MASKING NUDGES

To provide clarification on what a CMN is, as well as the potential ethical concerns such interventions might raise, it is useful to provide a brief introduction to nudging. Nudges were first proposed by Cass Sunstein and Richard Thaler as noncoercive interventions to improve individual wellbeing and decision-making, supported by their proposed doctrine of libertarian paternalism.[70] Drawing on insights from behavioral economics suggesting that human decision-making is plagued by systematic cognitive biases and irrational decision-making heuristics, nudges trigger or tap into these biases or heuristics to help people make better decisions for themselves.[71] A nudge is "any aspect of

66. *Genomic Data Sharing*, *supra* note 59.

67. Zubin Master et al., supra note 63.

68. *Id.*

69. *Genomic Data Sharing*, *supra* note 59.

70. THALER & SUNSTEIN, *supra* note 1, at 6.

71. *See, e.g.*, DANIEL KAHNEMAN, THINKING, FAST AND SLOW 13–14 (2011) (describing the tension between fast and slow thinking and how this interaction impacts choices).

the choice architecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives."[72] This is distinct from more familiar methods of persuasion, incentives, and coercion. Proponents of nudging claim that it is particularly useful when decisions "are difficult, complex, and infrequent, and when they have poor feedback and few opportunities for learning," and when choice architects can "make good guesses about what is best for the Nudgees"—two conditions likely to be met in medical research.[73]

A classic example of a libertarian paternalist nudge is changing the location of food in a cafeteria so that healthy options are at eye-level and unhealthy ones are less conspicuous.[74] The idea here is that while many people claim they want to eat healthier, when the time comes to do so, they are more likely to opt for what is easily accessible and in front of them rather than choose what will promote these ends, especially when they are hungry and faced with several ready-made but unhealthy options.[75] In other words, although people value and care about healthy eating, they tend not to choose foods in ways that promote or align with these values, due, perhaps, to fast and unconscious decision heuristics or weakness of will.[76] Nudging is proposed to help people overcome those failures and make choices that better promote or align with their values by intentionally modifying the location of healthy foods in cafeterias. Since we know that people are likely to choose what is salient and easily accessible, we can exploit that simply by changing the items that are most prominent from, say, pastries and candy bars to apples and pears.[77] This nudge is *libertarian* in the sense that it is noncoercive. People are free to resist the nudge if they want to badly enough: unhealthy foods are still available to purchase at the cafeteria; they are just less salient.[78] But this nudge is also *paternalistic* in the sense that modifying the location of foods has the predictable and intended effect of directing people to make healthier choices.

Sunstein and Thaler claim that "to count as a mere nudge, the intervention must be easy and cheap to avoid."[79] In order words, nudges must be easily resistible. Sunstein and Thaler distinguish nudges from other ways of influencing choice, such as providing information or attempting to persuade, as well as from

72. THALER & SUNSTEIN, *supra* note 1, at 6.

73. *Id.* at 247.

74. THALER & SUNSTEIN, *supra* note 1, at 1–6.

75. *See id.* at 41 (describing how different states of arousal impact our decisions).

76. *Id.* at 49.

77. *Id.* at 25, 49.

78. Jennifer Blumenthal-Barby, *On the Ethical Criteria for Health-Promoting Nudges: The Importance of Conceptual Clarity,* 19 AM. J. BIOETHICS 66, 66 (2019). A nudge might be easily resistible in the sense that (a) it is easy to tell one is being nudged and ignore the influence or (b) it is easy to act in a way other than what the nudge promotes. *Id.*

79. THALER & SUNSTEIN, *supra* note 1, at 6.

more familiar instances of paternalism that coerce people to act in ways that promote their own interests by eliminating options or imposing significant costs on certain choices.[80] For example, laws that require the use of seatbelts in cars and helmets by those riding motorcycles are paternalistic; they are intended to promote or protect the interests of people who ride in cars or on motorcycles.[81] But people are not free to disobey these laws without incurring significant penalties.[82] Nudges involve a weaker form of paternalism, in that they are noncoercive and influence choice—not by actually removing certain options or attaching significant penalties to them, but rather, by altering the presentation of options in a way that influences choice in a predictable way. Recall our cafeteria example. The libertarian paternalist does not advocate for tripling the price of unhealthy items or ceasing to sell them at all. All she advocates for is changing the location of items to make certain options more or less salient to her hungry customers.

Some might claim that CMNs cause trouble for the "libertarian" part of libertarian paternalism. Aren't nudges that mask available options significantly different than nudges that simply change the location or salience of options, since the former involve something like intentionally hiding available options while the latter does not? We aver that CMNs still qualify as "libertarian" (in the sense that they respect individuals' autonomy and freedom to choose). While certain choices are masked and so not listed on the menu of options, masked options are still easily available to those who seek to access them, and the possibility of opting-out should be sufficiently clear to those who wish to exercise it. What is and is not being masked is crucial in our analysis of CMNs. To be defensible, information about masked options and how to access them must be easily available. Only then does a CMN meet the resistibility requirement.

Rearranging foods in a cafeteria so that people make healthier choices for themselves will strike most as an innocuous intervention. And indeed, the classic examples that proponents of nudges appeal to when introducing and motivating this novel policy tool tend to be similarly innocuous. Sunstein and Thaler talk about nudging more employees into saving for retirement by changing the default enrollment from opt-in to opt-out, or restaurants serving food on smaller plates to make diners believe they are eating more than they actually are.[83] But some proposed uses of nudges are more controversial. Such controversial nudges extend beyond low-stakes decision environments like cafeterias and into high-stakes decision environments like exam rooms, where patients might be nudged into choosing a treatment by a physician who frames the risks and benefits of

80. *Id.* at 11.

81. Gerald Dworkin, *Paternalism*, *in* MORALITY AND THE L. 181, 182 (Richard A. Wasserstrom ed., 1971).

82. *Id.* at 188.

83. THALER & SUNSTEIN, *supra* note 1, at 108–10.

that treatment in a particular way.[84] Moreover, not all proposed uses of nudges are intended to benefit the individual who is nudged. For example, consider opt-out systems for organ donation that default drivers into becoming an organ donor—increasing the supply of organs surely benefits society as a whole, but it is hard to see how such a nudge could benefit the donor directly. Exactly who benefits from nudges is an important issue and in what follows, we will argue that nudges that are intended to benefit the individual who is nudged are easier to justify than nudges that are supposed to benefit someone else, or society as a whole. All three circumstances, however, are justifiable, provided they meet our acceptability conditions.

The ubiquity of nudging makes sense once we recognize that the features of decision making that make us susceptible to nudges are present whenever we make decisions. We cannot help but be influenced by the way things are presented to us, nor can we help but interact with a world that is presented in one way rather than another. Sunstein and Thaler term this the "inevitability" of choice architecture and its influence: people have to make decisions, and it is not as if there is some neutral way of arranging things that will have no effect on the decisions people ultimately make.[85] There is no such thing as a neutral way of presenting or framing choices, since how choices are presented or framed will inevitably affect what people choose. If those who are in a position to arrange choices cannot help but to exert some influence, then does it not make most sense to arrange things in a way that is likely to steer people towards good choices and away from bad ones? Indeed, this appeal to the inevitability of influencing is often a powerful response to those who argue that nudges are objectionably manipulative.[86]

Even if we cannot help but influence peoples' decisions in some way, and even if nudges are noncoercive and so are in this sense less objectionable than strongly paternalistic interventions, nudges still involve an intentional manipulation of the environment: choice architects steer people toward certain choices and away from others. This sort of meddling cries out to many as standing in need of justification. Thankfully, proponents of nudges have had a lot to say in their defense.

84. Moti Gorin et al., *Justifying Clinical Nudges*, 47 HASTINGS CTR. REP. 32, 33–34 (2017).

85. Cass Sunstein & Richard Thaler, *Libertarian Paternalism*, 93 AM. ECON. REV. 175, 175 (2003) [hereinafter *Libertarian Paternalism*].

86. *See id.* at 176–77 (discussing how the cafeteria example showcases inevitability when default options are required)*; see* Cass Sunstein, *The Ethics of Nudging*, 32 YALE J. ON REGUL. 413, 421–22 (2015) [hereinafter *The Ethics of Nudging*] (using nature and common law to show that "choice architecture is inevitable"). *But see* Kevin Vallier, *On the Inevitability of Nudging*, 14 GEO. J. L. & PUB. POL'Y 817, 818–19 (2016) (noting that "shaping," as opposed to nudging, uses decision making flaws, not persuasion, to influence choices); David M. Hausman & Bryan Welch, *Debate: To Nudge or Not to Nudge*, 18 J. POL. PHIL. 123, 133–36 (2010) (finding that nudges are "largely cases of rational persuasion").

First, as we have seen, nudges promote beneficial outcomes. Effectively implemented nudges help people make choices that may benefit them: they eat healthier, save for their retirement, enroll in health insurance, and make contributions to their pension plan.[87] Many people prefer these things for themselves but will not take action to bring them about due to the operation of cognitive biases or heuristics. Effectively implemented nudges also help people make choices that make other people better off: they become organ donors and safer drivers, they donate to charity, they prescribe their patients generic versions of drugs rather than the more expensive brand names and speak to their patients about their goals and values for end-of-life care.[88] And finally, effectively implemented nudges also help people make choices that promote public goods: they litter less, recycle more, and use less energy.[89] Nudges can play an important role in helping to bring about these important beneficial outcomes.

Second, nudges respect freedom of choice. Nudges influence choice, not by changing the menu of available options or by significantly changing economic incentives by making some available options significantly more expensive than others, but rather by changing the way options are presented or framed, thus respecting freedom of choice.[90]

Finally, survey evidence suggests that people do not mind nudges and actually prefer nudges to other, stronger forms of influencing choice, at least when they endorse the goals the nudges are intended to promote.[91] For example, there is survey evidence illustrating that in liberal democracies, strong majorities approve of nudges that protect and promote health and safety, as well as those that protect the environment, and that they prefer these to more coercive laws that promote those same goals.[92] Interestingly, the hypothetical nudges that individuals were surveyed about generally concerned public health outcomes—such as efforts to prevent obesity, limit salt consumption, discourage tobacco use, and reduce deaths from distracted driving.[93]

87. THALER & SUNSTEIN, *supra* note 1, at 5–6.

88. Jennifer L. Matjasko et al., *Applying Behavioral Economics to Public Health Policy: Illustrative Examples and Promising Directions*, 50 AM. J. PREVENTATIVE MED. S13, S16–S18 (5 Supp. 1, 2016).

89. *See* Alcott & Rogers, *supra* note 3, at 3025–29 (finding that the use of advertising and capital stocks alerted people to energy conservation).

90. *Libertarian Paternalism*, *supra* note 85, at 175.

91. *See* Dragos Petrescu et al., *Public Acceptability in the UK and USA of Nudging to Reduce Obesity: The Example of Reducing Sugar-Sweetened Beverages Consumption*, 11 PLOS ONE 1, 1–2 (2016); *see also* LUCIA A. REISCH ET AL., *Most People Like Nudges—and Why that Matters, in* THEORIES OF CHOICE: THE SOC. SCI. AND THE L. OF DECISION MAKING 73, 85–86 (Stefan Grundmann & Philipp Hacker eds., 2021).

92. REISCH ET AL., *supra* note 91, at 85 (noting that survey participants were asked whether they approved or disapproved of 15 hypothetical nudges and none of the hypothetical nudges seemed to be a CMN).

93. Cass R. Sunstein, *Do People Like Nudges?*, 68 ADMIN. L. REV. 177, 191 (2019) [hereinafter *Do People Like Nudges?*] (referencing Table 3).

IV. THE REASONABLE PERSON STANDARD AND RESEARCH REGULATIONS

The proposal to use CMNs in medical research might initially appear to directly contradict the requirements of full disclosure that came to dominate the informed consent jurisprudence in clinical care and medical research in the mid-twentieth century. However, we have reason to believe that CMNs *are* compatible with existing jurisprudence and legal norms. Our arguments depend on two claims: first, that there is a key difference between choices that have significant bodily autonomy implications and those that are primarily informational; and second, that disclosure requirements do not necessarily require the presentation of explicit choices about the information disclosed. In this Part IV, we argue that the aim of the reasonable person standard, properly understood and applied to the kind of informational decisions in medical research that we are concerned with here, supports CMNs (even if it may have legitimately been taken to support full disclosure requirements in other contexts). Because this standard is part of the United States federal regulations governing research and because the reasonable person standard is so deeply embedded in the American legal tradition,[94] a justification for CMNs that appeals to the reasonable person standard also fits into that tradition.[95]

A. Informed Consent Jurisprudence Supporting Full Disclosure

Informed consent jurisprudence from the second half of the twentieth century is characterized by landmark decisions underscoring the importance of physicians disclosing relevant medical information to their patients.[96] The cases that make up that jurisprudence typically involved physicians failing to inform patients of bodily harm risks that subsequently materialized.[97] In early informed consent cases, the patients' right to full disclosure was ostensibly grounded in their right to bodily integrity.[98] That autonomy interest was sufficiently

94. Dennis J. Mazur, *Influence of the law on risk and informed consent*, 327 BMJ 731, 731–32 (2003).

95. *See* Robert Unikel, *"Reasonable" Doubts: A Critique of the Reasonable Woman Standard in American Jurisprudence*, 87 NW. U. L. REV. 326, 327 (1992) (noting that reasonableness has been used in American jurisprudence for at least 140 years).

96. *See* Salgo v. Leland Stanford Jr. Univ. Bd. of Tr., 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) ("In discussing the elements of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."); *see also* Berkey v. Anderson, 82 Cal. Rptr. 67, 77 (1969) (stating that the doctor-patient relationship is fiduciary in character and for that reason requires "full disclosure").

97. Christine S. Coca Nour, *Informed Consent - It's More Than a Signature on a Piece of Paper*, 214 AM. J. SURGERY 993, 996 (2017).

98. *See* Mohr v. Williams, 95 Minn. 261, 217 (1905) (establishing the right to bodily integrity at the beginning of the 20th century); *see also* RUTH FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT 142 (1986) (noting that, "[c]ivil liberties, self-determination, fraud, bodily integrity, trespass, the fiduciary relationship, contract, and the like were all staples of the law," surrounding informed consent for decades in the 1900s).

important to ground the right to be informed about actions that may infringe it, and to be presented with an option to not participate in invasive medical procedures. But the right to bodily integrity can be meaningfully analyzed in terms of the reasonable person standard (RPS), as later informed consent rulings have done.[99] Intuitively, a reasonable person would expect full disclosure of relevant treatment options and risks in a situation where her bodily autonomy is at stake.[100] A standard of reasonableness would also give a research participant claims to a high level of explicit choice regarding decisions with bodily autonomy implications. Understanding the informed consent requirements in terms of the RPS is helpful because it offers guidance even in cases of research questions that do not obviously pose threats to bodily autonomy, as is the case for many of the informational choices we consider in this paper as candidates for CMNs.

B. The Reasonable Person Standard and Medical Research Nudging

Before returning to our argument regarding the RPS and CMNs, it is worth making some more remarks about the reasonable person standard. The difficulty of creating rules that will be appropriate in every context has long been acknowledged.[101] The RPS responds to this challenge by building flexibility into rules so their guidance may remain relevant, despite changing social contexts. In fact, the content of the RPS cannot be precisely pinned down by law because it refers to social facts beyond the reach of legislation.[102] The standard is widely accepted in a variety of legal applications, including negligence, contract, administrative law, judicial review, and criminal law.[103] A typical definition of the reasonable person standard describes "an imaginary actor who represents the community consensus of acceptable or appropriate behavior. This consensus establishes neither a standard of what average persons do nor an aspirational ideal beyond the reach of most persons, but a minimum threshold below which

99. *See* Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972) (analyzing informed consent disclosure requirements in terms of the RPS, the first case to explicitly refer to the RPS instead of other justifications like bodily autonomy).

100. *See* Danielle Bromwich & Joseph Millum, *Disclosure and Consent to Medical Research Participation,* 12 J. MORAL PHIL. 195, 197–99 (2015) (claiming that adequate disclosure is a necessary (if not sufficient) requirement of valid informed consent, and disclosing the information that a reasonable person would expect to be told is sufficient to satisfy the disclosure requirement).

101. *See, e.g.,* ARISTOTLE, NICOMACHEAN ETHICS 99 (Lesley Brown ed., David Ross trans., Oxford U. Press 2009) ("The reason is that all law is universal but about some things it is not possible to make a universal statement which will be correct.").

102. John Gardner, *The Many Faces of the Reasonable Person*, 131 L. Q. REV. 563, 571 (2015) ("[T]he zone of the reasonable person . . . is a legally deregulated zone in the sense that the law leaves it to be determined as a question of fact, not a question of law, how the law (meaning other law apart from the law which is currently being applied) is to be counted inside that zone.").

103. *Id.* at 570.

the ordinary person may not fall without being found deficient."[104] Despite some disagreement on the nature of the RPS,[105] experts generally agree that the standard must be applied on a case-by-case basis[106] and that it includes a range of behavioral standards.[107] Ultimately, the RPS provides instructions on making judgements about what a reasonable person would do, and its legal prominence gives those judgements legal weight. Standards set by the RPS, formulated in this impersonal way, "do not bend to the varying personal characteristics of those who are judged by them."[108]

Nevertheless, describing how the RPS is used does not tell us what it means to be reasonable. One suggestion from philosophical literature comes from Thomas Scanlon, who notes that a reasonable person must both consider an appropriate body of facts to be relevant to the question at hand and engage in an acceptable pattern of reasoning on the basis of those facts.[109] This process should occur against the backdrop of acceptable general aims and concerns.[110] Importantly, reasonable does not mean self-interested; a reasonable person may sometimes recognize that others' interests override her own.[111] The reasonable person must have reasonable concerns and respond to them in a rational way. For our purposes in analyzing CMNs, this standard imposes some normative constraints on reasonable research participants. While they can and should be concerned with their own welfare and utility, research participants should also be responsive to social interests and to the interests of others, and the way they make decisions should reflect those considerations. Their reasoning should give appropriate—but not overriding—weight to social interest, and they should also strive to act in ways that they can justify. Fleshed out in this way, we have a somewhat clearer picture of what it means to apply a reasonable person standard to participants in medical research. And it should be unsurprising that as context—that is, the reasons one must respond to—changes, the most reasonable courses of action may change as well.

104. FADEN ET AL., *supra* note 98, at 29.

105. *See, e.g.,* Alan Miller & Ronen Perry, *The Reasonable Person*, 87 N.Y.U. L. REV. 323, 325 (2012) (discussing whether reasonableness should be a normative or positive concept in law).

106. *See* Larry A. DiMatteo, *The Counterpoise of Contracts: The Reasonable Person Standard and the Subjectivity of Judgment*, 48 S. C. L. REV. 293, 301 (1997) (using Professor David Slawson's comments on contracts that their meaning depends on the situation in which they are created, so as a result the reasonable person standard is "constructed on a case by case basis").

107. Stephen G. Gilles, *On Determining Negligence: Hand Formula Balancing, the Reasonable Person Standard, and the Jury*, 54 VAND. L. REV. 813, 817 (2001).

108. Gardner, *supra* note 102, at 27–28.

109. THOMAS SCANLON, WHAT WE OWE TO EACH OTHER 32 (Harv. Univ. Press, 1st ed. 2000).

110. *Id.*

111. *See, e.g.,* JOSEPH MILLUM, THE MORAL FOUNDATIONS OF PARENTHOOD 136–38 (2018) (noting that the reasonable subject standard suggests a decision maker who is not selfish and instead "takes into account all the relevant practical reasons of which she is aware, prudential and moral," so the interests of others may sometimes take precedence over the subject's interest).

The RPS is helpful in explaining why the aforementioned body of jurisprudence that stresses the importance of informed consent may not translate directly to some contemporary medical research situations. The key contextual difference comes from the type of decision participants are asked to make in the research setting—specifically, whether they have immediate implications for bodily integrity or whether they are primarily informational.[112] Informational choices are less likely to infringe on a research participant's bodily integrity and more likely to affect individuals other than the nudgee than are physical choices, which primarily affect the research participant in an immediate bodily way. Potential benefit to others provides further support for informational nudges that are unlikely to be available for physical nudges. Reasonable disclosure and consent expectations where the physical consequences of medical research decisions are severe and individual decisions are not likely to significantly affect others, we argue, differ from reasonable expectations in contexts where decisions carry minor risk of causing serious injury but could have important consequences for research participants, others, and society more broadly. The RPS would not necessarily require explicit disclosure of the choice hidden by CMNs for two reasons: first, the CMN should be accompanied by sufficient information for participants to realize they have the option of opting out of defaults and for them to make sense of the defaults they are being nudged toward; and second, the fact that a choice is masked is expected to be in the participant's best interests.

C. Regulations and the RPS

If the RPS can theoretically accommodate CMNs, the next question is whether existing regulations governing research with human subjects legally permit their use. In the United States, the revised Common Rule lays out detailed requirements for informed consent.[113] These regulations are interesting for our purposes because in addition to referring to RPS, they also seem to allow for CMNs, provided that the CMNs do not also mask important information.[114] The most general level of guidance from the Common Rule focuses on ensuring that research participants are provided with enough information and opportunities for discussion to make informed decisions.[115] Note that the regulations do not

112. *See infra* Part II.A.

113. Off. for Hum. Rsch. Prots., *Clinical Trial Informed Consent Form Posting (45 CFR 46.116(h))*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html. *See* HHS General Requirements for Informed Consent, 45 C.F.R. 46.116 (2018) (detailing requirements for informed consent).

114. 45 C.F.R. § 46.116 (2018).

115. *Id.*

specify how that information be presented, or what kinds of choices must be made available, much less clearly communicated:[116]

> (a)(4) The prospective subject or the legally authorized representative must be provided with the information *that a reasonable person would want to have* in order to make an informed decision about whether to participate, and an opportunity to discuss that information….(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.[117]

The general guidance regarding information and understanding is followed by a more specific list of the kinds of statements and disclosures to be provided to research subjects.[118] Again, the regulations focus specifically on providing information in the form of statements and do not mention soliciting choices.[119] The regulations are oriented toward disclosing enough information for research participants to adequately understand what they are agreeing to participate in. One of our conditions on CMNs is that they must provide sufficient information to understand the implications of the default decision.[120] While CMNs involve masking some *choices*—specifically, by only presenting participants with a set of default options outlined in the consent form—they may not hide information relevant to the choice. In fact, providing such information is necessary to ensure that the default choice opt-out mechanism is robust. Since opt-out mechanisms rely on participants' self-identifying concerns with default options, they must be provided with enough information to be able to form an opinion about those options and be made aware that they can voice disagreement or discomfort at any time.[121] Since the informed consent regulatory requirements are silent on whether additional explicit choices—such as those that come after the primary decision to enroll in a study—must be presented as long as there is reasonable

116. Critics might object that it is only in the most literal interpretation of the letter of the law that these regulations could be seen as relating to information and not presentation of choices. But it is clearly within the spirit of the law to adjust to what is reasonable. If presentation of choices is restricted for reasonable reasons, there is no reason to think that it contradicts the spirit of the regulations, either.

117. 45 C.F.R § 46.116(a) (2018).

118. *Id.*

119. *Id.*

120. *See supra* Part IV.B.

121. *See supra* Part I (discussing CMN opt-out mechanisms).

disclosure, it seems entirely compatible with our presentation of CMNs. Ultimately, the RPS must be used to determine what qualifies as sufficient information. The revised Common Rule explicitly refers to the RPS because it is the standard-setter used to put these regulations into practice.[122]

D. Making Use of the RPS

A plausible picture of how the RPS could be applied to CMNs, consistent with prevailing United States research regulations, emerges from the above discussion. If we accept that a reasonable choice is one that balances interests and harms in a reasonable manner, we might accept something like the following: *medical researchers must present research participants with the choices that a reasonable person would have an interest in being able to make.* That stipulation prevents researchers from masking certain choices—specifically, ones ruled out by the autonomy and acceptability considerations articulated later in this paper—although it can at best be used as a rough heuristic, given the controversy over the definition of reasonableness. By the same token, we would also accept the similar claim that *medical researchers are not under an obligation to provide research participants with choices that no reasonable person could claim a right to make*. Such a position makes it clear that researchers have some discretion in which choices they present to research participants. Notably, while we understand the RPS as justifying masking the number of options presented to research participants, we do not take it to justify information masking. The balance of individual, collective, and social consequences of masking choices explain why it is reasonable to do so. In the situations we are interested in, masking information would not contribute to those positive consequences (and would infringe upon important autonomy interests), and thus would not be supported by the RPS.

V. AUTONOMY AND SELF-DETERMINATION

While bioethicists all agree that autonomy is an important ethical consideration, there are many different views about what autonomy is and what

122. 45 C.F.R § 46.116(a)(4). Interestingly, the revised Common Rule also describes instances in which the informed consent requirement may be waived or altered. 45 C.F.R § 46.116(e). Informed consent may not be required at all in cases where research involves no more than minimal risk, could not be carried out otherwise, will not affect the rights or welfare of participants, though it stipulates that participants should be provided with relevant information where applicable. 45 C.F.R § 46.116(b). The CMNs we propose meet those conditions, yet we still propose providing the disclosures required for informed consent. The fact that the regulations would countenance even withholding information in some situations suggests that our proposal to mask choice is not beyond the realm of what is already considered acceptable. *See* Joseph Millum & Danielle Bromwich, *Informed Consent: What Must Be Disclosed and What Must Be Understood,* 21 AM. J. BIOETHICS 46 (2021) (discussing disclosure and understanding in informed consent).

type of conduct violates it.[123] For our purposes, a rough and fairly intuitive characterization will suffice: autonomy is the capacity to be one's own person or to be the author of one's own life.[124] A person exercises her autonomy when her choices reflect, are based on, or align with, reasons, values, or preferences that are her own, rather than those that have been externally imposed on her.[125] We respect someone's autonomy when we let them choose for themselves, according to the things that matter to them, and accept the decisions that they make. The aim of this Part V is not to challenge the preeminence of autonomy or to endorse any particular account of it, but rather to argue that CMNs are at least compatible with many plausible views of autonomy and may even promote it. Ultimately, we maintain that whether a CMN is justified depends on a comparison of the benefits to be gained by nudging with the autonomy-costs that come from masking the choice. Relevant to this question, we shall argue, is whether the CMN satisfies the four conditions we lay out in Part VI. In our view, when these conditions are met, the benefits to be gained by masking a choice are sufficient to justify the cost to autonomy. Our primary concern is with helping research participants make good decisions that they care about, which can itself enhance autonomy.[126]

In this Part V, we will survey prominent accounts of what autonomy is and why we must respect it and argue that most of these views are compatible with CMNs. We acknowledge, however, that some accounts of autonomy sit less comfortably with CMNs. Specifically, CMNs might cause trouble for views on which respecting autonomy requires engaging with a chooser's deliberative capacities or ensuring that a chooser decides *on the basis of* information that is relevant to the choice. People who believe that respect for autonomy requires interacting with a chooser's decision-making capacities in this particular way are unlikely to accept our defense of CMNs. However, we suggest that the relevant question is not whether there is *any* cost to autonomy at all, but rather how significant that cost is, and whether the stakes of the choice are great enough that such an autonomy-violation is ethically unacceptable.

123. *Decision-Making - Module 3*, UNIV. OF MIAMI MILLER SCH. OF MED. INST. FOR BIOETHICS AND HEALTH POL'Y, https://bioethics.miami.edu/education/ethics-curricula/geriatrics-and-ethics/decision-making-autonomy-valid-consent-and-guardianship/index.html (last visited Dec. 10, 2021).

124. *See, e.g.,* John Christman, *Autonomy and Personal History*, 21 CANADIAN J. PHIL. 1 (1991) ("Virtually any appraisal of a person's welfare, integrity, or moral status, as well as the moral and political theories built on such appraisals, will rely crucially on the presumption that her preferences and values are in some important sense her own."); *see also* Harry Frankfurt, *Freedom of the Will and the Concept of a Person*, 68 J. PHIL. 6–7 (1971) (explaining that humans have the ability to make decisions based on their desires); JOSEPH RAZ, MORALITY OF FREEDOM, 369-424 (1988) (providing the definition for autonomy).

125. *See* Chris Mills, *The Heteronomy of Choice Architecture,* 6 REV. PHIL. AND PSYCH. 495, 496–97 (2015) (noting the language in the context of nudges).

126. *See* Cass Sunstein, *Autonomy by Default*, 16 AM. J. BIOETHICS 1, 1 (2016) [hereinafter *Autonomy by Default*] (discussing how nudges can enhance autonomy).

Though we defend CMNs in a variety of research settings and for a variety of decisions, we recognize the existence of a special domain of decisions that relate directly or are foundational to one's identity or deep moral commitments, and we claim that individuals ought not to be nudged regarding those decisions.[127] Consider, for example, a sincerely held religious belief about what makes life worth living or the sort of activities one ought never to engage in. Acting in accordance with those kinds of deep commitments fosters autonomous authenticity.[128] CMNs that nudge individuals to make decisions that go against those commitments, if effective, could make them feel complicit in something they consider morally reprehensible, resulting in feelings of moral distress and autonomy harm.[129] For example, imagine that someone who, for religious reasons, is morally opposed to genetic cloning is nudged into providing genetic material to a biobank primarily used to support research into cloning. Because her deep religious commitment against cloning is so central to her identity, the sense of moral harm from being nudged into contradicting it could constitute an autonomy harm. Plausible views of autonomy recognize this protected domain; the domain thus constrains the kinds of choices that we may permissibly mask.[130]

Even if the idea that such a protected domain exists makes sense in theory, however, respecting that domain poses serious practical challenges. For one thing, how can we evaluate the sincerity of individuals' identity-centric convictions? One individual's deep moral commitment is another's weak preference. Relatedly, how are we to respond to extremely uncommon religious beliefs or moral commitments that researchers are unlikely to anticipate? Some heuristics may reduce the extent of this problem. For example, it is easier to anticipate the deep convictions of groups than of individuals, because groups often publicly articulate their fundamental commitments. Self-identified group membership is thus a likely indicator of beliefs that fall within the protected domain, albeit an imperfect one. For some decisions, public survey data may be helpful in judging whether a particular view is common and deeply held—some surveys, for example, show that many people express deep discomfort with research into genetic cloning.[131] Researchers should make their best efforts to anticipate what kinds of CMNs are likely to involve nudging people into identity-formational decisions and consequently, should strive to avoid utilizing those

127. *See* Stephen Wall, *Perfectionism, Reasonableness, and Respect*, 42 POL. THEORY 468 (2014). These commitments are difficult to identify, and it is controversial whether they should be accorded such importance. *Id.* at 477–78.

128. *See, e.g.,* David Enoch, *Hypothetical Consent and the Value(s) of Autonomy*, 128 ETHICS 6, 30–34 (2017) (discussing the importance of authenticity, under the label "nonalienation").

129. *See* Stephen Campbell et al., *A Broader Understanding of Moral Distress*, 16 AM. J. BIOETHICS 2, 5 (2016) (discussing the effects of decision making on moral distress).

130. *Id.*

131. Philip Reilly, *Public Concern About Genetics*, 1 ANN. REV. GENOMICS AND HUMAN GENETICS 485, 488 (2000).

CMNs. The unfortunate fact that researchers may not always succeed doing so underscores the importance of ensuring that CMNs only mask information—not choices—and that easy opt-out mechanisms exist.

A. Genuine Choice

A prominent feature of many views of autonomy is the requirement that an autonomous individual possesses a genuine choice between a variety of different outcomes.[132] While few views on autonomy hold that genuine choice is entirely constitutive of autonomy, it is so often a prerequisite for autonomy that it warrants discussion on its own.[133] Genuine choice has two distinct components: availability of options and the freedom to choose between them.[134] A critic of CMNs might claim that these nudges should be rejected since they restrict both the set of available options and someone's freedom to choose from that set. If true, this objection would constitute a serious strike against the argument for using CMNs.

As is clear from their very name, CMNs attempt to make certain choices less apparent to those being nudged. Recall that the primary motivation for introducing CMNs was to *not suggest* certain options to individuals who did not have prior preferences about those options when those options are expected to have negative effects on the chooser or on others.[135] CMNs are not intended to *actually* reduce the chooser's option set—importantly, they must be easily resistible and include a clear opt-out mechanism—but they are undeniably intended to make the option set *appear* more limited.[136] The opt-out mechanism must be easy to locate for individuals who wish to choose a masked option. But what about the individuals who never seek an opt-out mechanism, regardless of whether they would have wanted it, because they do not realize that an option was masked in the first place? For individuals who recognize the CMN and take the easy, available steps to opt-out, the nudge clearly does not interfere with either component of genuine choice. The important question, therefore, is how significantly masking a) decreases the number of available options and b) interferes with the ability—for individuals who do *not* act to avoid the nudge—to choose.

132. *Autonomy*, WIKIPEDIA, https://en.wikipedia.org/wiki/Autonomy (last visited Dec. 10, 2021).

133. *See* RAZ, *supra* note 124, at 372 (finding that the autonomous person must have sufficient mental abilities to plan her life, she must make choices independently for herself, and she must choose from an adequate range of options); Enoch, *supra* note 128, at 32–33 (considering "sovereignty" and "nonalienation" to be key components of autonomy; both require having genuine choice in shaping one's life).

134. William James, *On the Will to Believe*, LUMEN, https://courses.lumenlearning.com/suny-classicreadings/chapter/william-james-on-the-will-to-believe/ (last visited Dec. 10, 2021).

135. *See supra* Part II.

136. *See infra* Part VI.C.

It seems unlikely that CMNs will affect the number of available options or research participants' ability to choose to such a degree as to make their choice nonautonomous. This claim may ultimately result in the need to compare the costs and benefits of the CMN and its effects on genuine choice. As we emphasized above, the sort of CMNs we aim to defend affect only the *appearance* of choice: to be justified, a CMN must not alter the underlying options and must be easily avoidable. In practice, the nudgee must be aware that some choices are being masked, and an easy way to avoid the nudge must be available if they seek it. Thus, we contend that if ethically acceptable CMNs restrict autonomy, this is only a minor restriction. And importantly, ensuring a maximal degree of autonomous choice is not the only desiderata for a CMN; it is also important that the nudge helps participants make *better* decisions in medical research. Thus, even if CMNs unavoidably represent some deviation from the genuine choice conception of autonomy, the safeguards that we stipulate ensure that they protect autonomy to a sufficient degree. When we compare the potential for a (slight) diminution of genuine choice with the benefits expected from an acceptable nudge, the CMNs seem justified.

B. Making Important Decisions

CMNs might also be criticized on the autonomy grounds that they prevent research participants from making important decisions for themselves, since being able to make certain important decisions is a prominent feature of some accounts of the ethical importance of autonomy.[137] On these views, what matters for autonomy is that the person makes the important choices that clearly shape the major features of their life. But not all choices are equally important in shaping a life. As we explained earlier in this Part V, we should not mask choices that relate to the protected domain of identity-related decisions; those kinds of choices are undoubtedly life-shaping.[138]

Making important decisions does not require that autonomous people have genuine choice over *every* decision they could possibly make. While respect for autonomy requires allowing individuals to make the most personal identity-forming decisions independently, many decisions in medical research are not of that type.[139] Just as we routinely accept that autonomy interests do not allow us to make all types of decisions in our everyday lives— such as which side of the street to drive on, whether to educate our children, and what we pay in taxes—

137. *See* RAZ, *supra* note 124, at 369 (noting autonomy is "the vision of people controlling, to some degree, their own destiny, fashioning it through successive decisions throughout their lives").

138. *See supra* Part V.

139. For example, participants are not generally consulted when logistical or technical choices need to be made about how research procedures are performed (e.g., size of needle, timing of administration, etc.). Participants also generally have no input core scientific questions (e.g., design of the protocol, recruitment strategies, decisions about halting or extending a study).

autonomy does not require that we make all types of decisions in medical research. Some constraints on choice are a necessary part of living in society and do not unduly impinge on autonomy.[140] Interestingly, this account of what matters for autonomy might supplement arguments for the use of CMNs.[141] Nudges that mask relatively minor choices could actually promote autonomy, then, by freeing individuals to expend their limited cognitive energy on decisions that are the most crucial to personal autonomy.

C. Understanding and Engaging with Options

Another way to think about how CMNs might infringe upon autonomy comes from the requirements of informed consent, a widely recognized and core tenet of medical ethics intended to ensure that research participants understand what they are agreeing to. Roughly, the idea is that obtaining informed consent is a good way to ensure that a participant's decision is autonomous—but only if the participant has sufficient understanding of the decision. Adequate understanding is one of the key requirements for informed consent outlined in Beauchamp and Childress's famous text outlining the basic principles of bioethics.[142] According to their view, autonomous choice requires not only a sufficient range of options, but also sufficient understanding of those options, as well the cognitive capacities that are necessary to make well-informed decisions on the basis of that understanding.[143] Further, one might add that it is not enough merely to understand the options and possess the necessary cognitive capacities to make well-informed decisions; one must also *engage* those cognitive capacities by deliberating over the available options before selecting one

This view of autonomy is concerned with the process of making a decision, and CMNs are admittedly more concerned with decision outcomes than with processes.[144] CMNs are not designed to be educative; their aim is not to inform or increase one's understanding, nor is it to make it more likely that people choose on the basis of relevant information.[145] Rather, CNMs aim to help people

140. *See* JOEL FEINBERG, THE MORAL LIMITS OF THE CRIMINAL LAW VOLUME 3: HARM TO SELF 38 (1989) (stating where there are "settled practices, defined by well-understood conventions," the autonomous person cannot simply "invent his own alternative rules for playing the public game").

141. *The Ethics of Nudging*, *supra* note 86, at 438 ("It is also important to see that autonomy does not require choices everywhere. It does not justify an insistence on active choosing in all contexts. If we had to make choices about everything that affects us, we would quickly be overwhelmed. There is a close relationship between time-management and autonomy. People should be allowed to devote attention to the questions that, in their view, deserve their attention. If people have to make choices everywhere, their autonomy is reduced, if only because they cannot focus on those activities that seem to them most worthy of their attention").

142. TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 1, 13 (8th ed. 2009).

143. *Id.*

144. *See supra* notes 48–49 and accompanying text.

145. *See supra* notes 48–49 and accompanying text.

make better choices, specifically by steering them away from choices that researchers have good reason to believe are bad.[146] So, if autonomy requires an understanding of the options that are available, being well-informed about the information that is relevant to a choice, deliberating, and ultimately choosing an option based on that relevant information, CMNs may threaten to infringe on autonomy because they cannot ensure that participants understand the default decisions they are nudged toward.

However, it is important to notice that this is not a knock-down argument against CMNs. For one thing, it is not obvious that slightly reducing people's information counts as a real cost to their autonomy. We typically do not believe that people always need to be informed about *all* the available options in order to act autonomously: what matters is that they are *sufficiently* informed. So, for example, we do not think that a clinical investigator infringes on the autonomy of their subjects by failing to tell their subjects the entire range of information that might somehow bear on their choice about whether to participate. Indeed, it is hard to see how a clinical investigator could do that and still have time to carry out any of their research. Rather, the investigator has an obligation to disclose all the information that they have reason to believe would be relevant to the prospective participant's decision.[147] The fact that a specific CMN exists may not be necessary to disclose if participants are informed that they may request modified treatment regarding default options they disagree with.[148] But, even if one resists this argument and thinks that providing less information always has some autonomy cost, the cost is likely to be quite low in the sorts of cases we are concerned with.[149] We are not proposing an insuperable barrier to people receiving the relevant information about alternative options, but we are requiring that they take an extra step. That is why CMNs are nudges, and not more stringent restrictions on choice. Since this cost is quite small, it is likely to be outweighed in most of the cases we are concerned with, either by the benefits of the nudge, or even other considerations of autonomy—for example, the fact that CMNs, when well-executed, can lead people to make choices that better align with their own values.[150]

D. Successfully Reaching One's Own Goals

A final way to understand autonomy draws on the distinction made between "means" and "ends" paternalism. Ends paternalism involves guiding people

146. *See supra* notes 48–51 and accompanying text.

147. BEAUCHAMP & CHILDRESS, *supra* note 142, at 123.

148. *Id.*

149. Moreover, this cost would be comparable to ways we regularly accept that living in society detracts autonomy.

150. *See Autonomy by Default*, *supra* note 126, at 63 (discussing the way in which nudges enhance patient autonomy).

toward goals that they do *not* identify as their own, whereas means paternalism involves guiding people toward goals that they *do* identify as their own.[151] Put slightly different, means paternalism assists people in taking the correct means to their own ends, whereas ends paternalism involves changing people's ends.[152] In his book, *Why Nudge?,* Cass Sunstein argues that we respect autonomy so long as we respect people's own ends.[153] In other words, as long as nudges are always instances of means paternalism, and never instances of ends paternalism, then we need not worry about whether those nudges respect autonomy because respecting autonomy is merely about "allowing individuals to make informed decisions about their own ends."[154] According to this view, in order to assess a nudge's impact on autonomy, all we must ask is whether the person who is nudged is "better off, as judged by themselves."[155] We decide autonomously when we ultimately get what we want, and we respect someone's autonomy when we help them get what they want.[156]

There are reasons to doubt that this account of autonomy really captures what it is to be autonomous, and therefore what it is to respect someone's autonomy. For one thing, the distinction between means and ends paternalism is not as sharp as this view might suggest. In many cases, participants will not have strong prior preferences about the options being masked or towards which they are being nudged.[157] Moreover, individuals adopt ends for a variety of reasons, including because of previous nudges or other social influences.[158] Self-proclaimed ends may reflect prior influences just as much as they reflect what is central to an individual's autonomy.[159] It is thus often unclear when nudges are more properly considered examples of ends or means paternalism.[160] As a result, this view of autonomy is only of limited usefulness in analyzing nudges.

151. CASS SUNSTEIN, WHY NUDGE? THE POLITICS OF LIBERTARIAN PATERNALISM 63 (2014).

152. *Id.* at 138.

153. *Id.*

154. *Id.*

155. THALER & SUNSTEIN, *supra* note 1, at 5.

156. *See, e.g.,* Jukka Varelius, *The value of autonomy in medical ethics*, 9 MED., HEALTH CARE AND PHIL. 377, 377 (2006) (stating that by making our own choices we are giving our lives "meaning, purpose, and distinctive uniqueness, and/or expressing ourselves").

157. *See* Tina A.G. Venema et al., *When in Doubt, Follow the Crowd? Responsiveness to Social Proof Nudges in the Absence of Clear Preferences*, 11 FRONTIERS IN PSYCH., no. 1385, June 2020, at 1, 2 (finding in a study where participants indicated no preference for one-sided or double-sided printing, the change in default settings to double-sided printing resulted in a 15 percent reduction in paper use).

158. SUNSTEIN, *supra* note 151, at 70.

159. *See* Venema et al., *supra* note 157, at 2 (finding "nudges are specifically designed for people who have adopted goals but fail to act upon them"). For example, "a prompt that encourages people to take the stairs instead of the escalators should be effective for people who think they should be more active, but not for people with walking disabilities." *Id.*

160. SUNSTEIN, *supra* note 151, at 75.

But leaving aside those concerns, it seems plausible that at least some CMNs are means paternalist and are therefore compatible with this view of autonomy. Returning to the RNTK case described in Part II.A, consider a nudge that masks the choice of whether or not to receive actionable secondary genetic findings.[161] While most people would prefer to avoid becoming incurably ill, when presented with a choice, some will elect not to receive these secondary findings, even though it may not align with their values and they may not choose to do so upon deeper reflection.[162] Masking this choice, then, would lead more people to receive secondary findings and would benefit most people. As long as we can be confident that masking a choice will significantly decrease the chance that people choose badly—that is, choose an option that will make them worse off, as judged by themselves—then doing so might not disrespect autonomy. In fact, according to some views, nudges could even turn out to be autonomy *enhancing*.[163] If autonomy is respected when people make choices that reflect their own values—and since people sometimes predictably choose in ways that do not promote their own values—then nudges could be considered autonomy-enhancing if and when they help a nudgee choose in accordance with their own values.[164]

This approach raises a number of questions, however; most notably including how to respond to the minority of individuals on the tail end of the curve who genuinely do not identify with the aims of the nudge.[165] Is the fact that a nudge is means paternalistic for most individuals enough for a nudge to be considered means paternalistic overall? Even if there are some things that almost everyone values, people vary tremendously in the trade-offs they are willing to make. Taking this inevitable variation seriously should lead us to be skeptical about the idea of a "one-size-fits-all" nudge that somehow manages to be sensitive to this variation and steers people toward choices that facilitate them getting what they really want.[166] Exactly how is a choice architect able to access this information about each person whose choice is affected by the nudge, especially when they do not themselves have self-knowledge about what they really want or what would really make them better off? These are deep and

161. *See supra* Part II.A.

162. *See supra* Part II.A.

163. Varelius, *supra* note 156, at 382 ("Indeed, if others are more capable of getting the kind of results that the person wants, the person who lets others make her own choices for her can thereby become even more autonomous than she was to begin with.").

164. *See* Mills, *supra* note 125, at 496–498 (defending nudges by appeal to autonomy enhancement); *see also* Cass R. Sunstein, *Choosing Not to Choose*, 64 DUKE L. J. 1, 39 (2014) [hereinafter *Choosing Not to Choose*].

165. *See* Schupmann et al., *supra* note 29 (demonstrating that minority individuals genuinely do not want to learn potentially lifesaving information).

166. *See* DiMatteo, *supra* note 106, at 301 (explaining that the reasonable person standard must be established on a case-by-case basis).

interesting questions, and they raise issues for many of the views of autonomy discussed here. Our hope is that the acceptability conditions for CMNs that we outline in Part VI help to answer them, at least for the nudges we aim to defend.[167]

This Part V described commonly held beliefs about the importance of autonomy and argued that as long as CMNs do not intrude on protected identity-forming spheres, they are compatible with respecting individual autonomy. However, showing that compatibility is not yet enough to justify CMNs. Part VI identifies the further features of CMNs that are necessary to make them acceptable, particularly in the research context.

VI. NON-AUTONOMY ACCEPTABILITY CONSIDERATIONS FOR CHOICE-MASKING NUDGES

While autonomy is an important consideration relevant to justifying the kind of informational nudges we are primarily concerned with here, it is not the only one.[168] In this Part VI, we focus on four further considerations, all of which must also be met for a CMN to be ethically acceptable.[169] Acceptability comes on a continuum, and nudges toward certain types of research—such as research with vulnerable populations or research on ethically controversial topics such as cloning—may need to satisfy especially stringent acceptability conditions.[170] While the stringency of each consideration will vary with context, the following four considerations give a rough indication of how acceptable any CMN is likely to be. First, the nudge must be in the service of legitimate policy goals. Second, the nudge must result in significantly more benefits than harms, overall. Third, while nudges may have associated burdens, those burdens cannot be distributed unfairly. And fourth, for a CMN to be acceptable, it must be better than other feasible alternative ways of achieving the same goals. There are two components to CMN acceptability: first, the nudge must not be objectionable on autonomy grounds and second, it must satisfy the four considerations described below.

167. *See supra* Part VI.

168. *See supra* Part II. Non-autonomy concerns are especially important for choices that have significant informational (as opposed to physical) components. *See supra* Part II.

169. *See supra* Part VI.

170. *See* Christine Grady et al., *Broad Consent for Research with Biological Samples: Workshop Conclusions*, 15 AM. J. BIOETHICS 34, 39–40 (2015) (discussing when broad consent is appropriate). Certain topics may be so sensitive that they call for providing extra information with the nudge. *Id.* Doing so is not a paradigmatic choice masking nudge and may reduce the extent to which a choice is masked. *Id.*

A. Legitimate Policy Goals:[171]

There are three levels on which a CMN policy goal can be legitimate: individual, collective, and societal. The idea that health promotion has a special status because of health's fundamental role in furthering human activities colors the discussion of CMNs policy goals at all levels.[172] That important role, we argue, is sufficient to ground a legitimate interest in promoting health—and, by extension, medical research.[173] First, on an *individual* level, it could be intended to benefit nudgees since they, themselves would endorse or otherwise approve of the underlying goal. Second, there is a broader *collective* basis of legitimacy goals for CMNs; some policy goals might be worth pursuing even if not every individual nudged by them would agree that the nudge makes them better off. CMNs can be justified on a collective level when most individuals who will be nudged agree with the goals that the nudge is intended to promote. Finally, CMNs can be justified on a societal level when they lead to consequences that benefit society or when they express important social values and attitudes. Though all three levels can provide sufficient justification for a CMN, as one gets further away from direct individual benefit, the threshold for justification increases.

Policy goals that are legitimate because of expected individual benefit are relatively straightforward to analyze. The most direct benefits from a CMN come from encouraging research participants to make decisions that they otherwise would not have made, and that have positive consequences.[174] For example, consider a participant who is nudged away from choosing to refuse secondary findings and who as a result, learns that her genome sequence contains evidence of high risk for Hereditary Non-Polyposis Colon Cancer, which she later develops.[175] After receiving information about her hereditary risk, she would be more likely to undergo enhanced routine screenings which would result in

171. Our arguments in this section respond to ethical rather than legally compelling interests. And while we write of policy goals, we recognize that nudges will often be carried out by non-governmental institutions.

172. *See* NORMAN DANIELS, JUST HEALTH 21 (2007) (explaining that health is of special moral importance because it contributes to the range of opportunities open to us); *see also* Hafez Ismaili M'hamdi, *Neutrality and Perfectionism in Public Health*, AM. J. BIOETHICS 31, 31 (2021) (advocating for a defense of health policy as a legitimate state goal).

173. A CMN's legitimate health interest plays a role similar to a state's legitimate interest in the rational basis test of judicial scrutiny. *See Rational Basis Test*, CORNELL L. SCH. LEGAL INFO. INST., https://www.law.cornell.edu/wex/rational_basis_test (last visited Jul. 26, 2021) (describing the Rational Basis Test). For a state statute or ordinance to be shown to be constitutional, it is sufficient (as long as the statute or ordinance does not infringe upon fundamental constitutional rights) to show that there is a rational connection between the policy or ordinance and the state interests. *Id.* Similarly, since we have excluded CMNs that infringe upon individuals' identity-foundational commitments, showing that CMNs are rationally related to health promotion should be sufficient to show their policy goals to be legitimate.

174. *See supra* notes 50–51 and accompanying text.

175. Berkman, *supra* note 28, at 7.

detection and treatment of the cancer at an early stage.[176] Without the genetic indication, the cancer, which is difficult to detect with only normal colonoscopies, would likely not be detected until a later and more fatal stage.[177] Thus, the nudge could yield a direct benefit to the nudgee herself.

In these cases, a CMN can steer someone towards a potentially life-saving decision that they otherwise might not have made but would have chosen if they had all necessary information and were perfectly rational. This is not a hypothetical concern: there is evidence that people regularly choose not to learn about secondary findings without fully understanding what they are actually refusing. Consider data from a recent empirical study on the RNTK in which a large environmental health study asked 8,843 participants if they would like to receive secondary genetic findings ("SFs"); 165 declined.[178] In a later sub-study, these "initial refusers" were given slightly more information about SFs and were given another opportunity to make a decision.[179] The results were stark, indicating a sizeable group of "weak refusers":

> …almost half of participants who initially refused SFs subsequently accepted them. By soliciting preferences through check boxes after an accurate but limited presentation of information, it is likely that some participants will make a choice that results in forgoing potentially life-saving information that, upon further reflection, they would have wanted to receive.[180]

The decision to give participants a choice about whether to accept SFs introduced a risk: some participants might refuse to receive them. In such a scenario, a CMN that defaults participants into receiving these findings would mitigate that risk by guiding weak refusers towards a decision that is consistent with their own preferences and interests.[181]

On a collective level, a CMN can be justified if it benefits most participants. Benefits should be recognized and taken into consideration even when they accrue to someone other than the individual being nudged, or when the beneficiaries of the nudge cannot be directly identified. CMNs are carried out on

176. *Id.*

177. *Id.*

178. Schupmann et al*., supra* note 29, at 2.

179. *Id.*

180. *Id*. at 4.

181. Nudging someone towards acceptance of important medical information is predicated on the assumption that they could then take medical action to address the health concern. This assumes a baseline level of access to medical care, which will not always be true in low resource settings, and which could reduce the ability to justify a CMN. *See, e.g.,* Haley K. Sullivan & Benjamin E. Berkman, *Incidental Findings in Low Resource Settings* 48 HASTINGS CTR. REP. 20 (2018) (arguing that incidental findings in low resource settings are imperative for medically important results in genetic research). Nudging someone towards acceptance of important medical information is predicated on the assumption that they could then take medical action to address the health concern.

an institutional level, not at the level of individual interactions.[182] Thus, it will often not be feasible to nudge only some members of a targeted group; a nudge has the potential to affect the decisions of all who interact with it—those it will benefit *and* those it will not. It is enough to show a benefit if implementation of a CMN makes it more likely that most participants will act in accordance with the nudge; it is not necessary that the nudge is beneficial from the perspective of each individual being nudged. For instance, when we consider the RNTK case, we see that, although most participants would prefer to avoid becoming incurably ill, some participants might have principled reasons for deciding to opt-out of receiving SFs. For example, some people might worry that documentation of a potentially pathogenic genetic variant will make it harder for them to obtain certain kinds of insurance (such as health, life, and long-term care). If it is not possible to select only amenable nudgees, then applying the nudge to its intended audience will also involve applying the nudge to individuals outside of its intended audience.[183] We argue that nudging individuals who would prefer not to be nudged can be justified by the benefits that the nudge brings to others who are amenable to the nudge.

On a societal level, nudges may have legitimate policy goals even when nudgees do not have preferences about the goals (and would not, even if fully informed), provided that the goals serve an important societal purpose.[184] For example, current genetic reference data skews heavily toward white individuals of European ancestry.[185] As a result, genetic research findings may be less applicable to non-white individuals.[186] If genetic reference data were more broadly representative, it would have more value for more of the global population. The social good of having a diverse bank of genetic reference data could be a legitimate policy goal and justify a choice-masking nudge that urges individuals to contribute to such reference data banks, even if donors of that information are not likely to be directly benefited by the research it enables. Many social goals that will be valuable to large groups of people, now or in the future, do not directly benefit every individual who could help promote those

182. *See* Stuart Mills, *The Future of Nudging Will Be Personal*, BEHAV. SCIENTIST (Mar. 15, 2021), https://behavioralscientist.org/the-future-of-nudging-will-be-personal/ (describing the different outcomes of population-level nudges versus individual-level nudges).

183. Linda Thunstrom, Ben Gilbert & Chian Jones Ritten, *Nudges that Hurt Those Already Hurting: Distributional and Unintended Effects of Salience Nudges*, INST. FOR PUB. RELS. (Aug. 18, 2020), https://instituteforpr.org/nudges-that-hurt-those-already-hurting-distributional-and-unintended-effects-of-salience-nudges/.

184. *See generally* Muireann Quigley, *Nudging for Health: On Public Policy and Designing Choice Architecture*, 21 MED. L. REV. 588 (2013) (describing how nudges can impact behavior to improve public health).

185. *See* Giorgio Sirugo et al., *The Missing Diversity in Human Genetic Studies*, 177 CELL 26, 27 (2019) (finding in 2018, 78% of the individuals included in genome-wide association studies were of European ancestry).

186. *Id.*

goals. Important social goals are still legitimate to pursue, and we see no principled reason why nudges cannot be used to promote them. When the individuals being nudged do not have strong preferences about the policy goal being promoted by the nudge, the societal legitimacy of the goal plays a greater role in justifying the policy goal.[187]

Some people might worry that using legitimate policy goals as a justification for paternalistic CMNs is a dangerous move that opens the door to using CMNs in service of any frivolous policy aim that can be shown to be means-paternalistic[188] to most affected individuals or to promote a valid social goal that people do not oppose. This concern shows that policy aims of CMNs could become increasingly difficult to justify the farther away they move from providing direct individual benefits.[189] In response to these concerns, we emphasize that legitimate policy goals are a necessary, but not sufficient, condition for acceptable nudges. The considerations described in the remainder of this Part V deal with concerns about using nudges for trivial reasons.

B. The Benefits Outweigh the Harms

In assessing the balance of benefits and harms from a CMN, we are interested in the direct and indirect effects on all people potentially impacted by the nudge. In the previous section, we began outlining the idea that the justificatory threshold will increase as the consequences of the nudge become further removed from the nudged individual.[190] For purposes of assessing benefits and harms, consequences that accrue directly to the research participant being nudged (the individual level) should be given the most weight. Broader social benefits and harms (the societal level) should be given less weight to reflect the less direct link between the nudgee's decision and the ultimate goal, and because any individual's marginal contribution to the larger social project will be less significant. Benefits and harms to third parties (the collective level) will fall somewhere in between, and the weight in these cases will depend on how direct the connection is between the CMN and the effect on the third-party. For a nudge to be acceptable, the aggregate benefits—weighted by their proximity to the individuals being nudged—must be greater than the similarly weighted aggregate harms.[191]

187. *See* Venema et al., *supra* note 157, at 9 (finding that a "nudge is effective in guiding people's choices particularly when they do not know what to choose and that a nudge has the potential to reduce uncertainty.").

188. *See supra* Part V.D.

189. *See supra* Part V.D.

190. *See supra* Part VI.A.

191. *See infra* Part VI.C. (discussing burden distribution). Although, as we will discuss in the next section, even if the harm/benefit calculus is favorable in the aggregate, harms also must not be distributed unfairly. *See infra* Part VI.C.

The various types of benefits that follow CMNs are described in the section above as the bases for different levels of legitimate policy goals.[192] If a particular aspect of medical research can be reasonably expected to promote health (individually, collectively, or societally), there is at least a presumptive expectation that nudges that advance research have some important benefits.[193] We are concerned here with potential CMN-related harms of three types: economic, psychosocial, and harm to trust.[194] While research suggests that the importance of the former two concerns may be exaggerated, harm to trust in medical research is concerning—both in itself and because of its potential impact on health-seeking behavior and subsequent negative effects on health outcomes.[195] Complicating matters, the risk-benefit analysis becomes less certain when examining contexts like NBS and GDS, where the CMN produces less direct societal benefits.[196] The marginal contribution of any individual sample or data set will be minimal, but the aggregation of these resources can result in substantial benefit.

A final category of harm that we will not discuss here is harm associated with masking an important identity-foundational choice, whose forced selection could significantly undermine a nudged research participant's sense of self. Such harms are unlikely to occur from choice-masking nudges that refrain from nudging around sensitive identity-foundational areas, as we stipulate that CMNs must.[197] It is possible, however, that even nudges that avoid masking most sensitive choices may have this kind of effect on a small number of participants. That potential harm can be minimized by making the CMN resistible and by flagging—as clearly as possible—the underlying conditions or beliefs that might make a particular nudged option inappropriate. It is unlikely that nudges satisfying all four acceptability considerations laid out in this Part VI will lead to serious harms.

1. Economic and Psychosocial Harms

Economic and psychosocial harms are adverse consequences that should be avoided, but we are skeptical that otherwise acceptable CMNs would likely lead to serious harms of either kind. To illustrate potential economic and psychosocial harms that could come from CMNs, consider the RNTK empirical study

192. *See supra* Part VI.A.

193. *See* Sze Lin Yoong et al., *Nudge strategies to improve healthcare providers' implementation of evidence-based guidelines, policies and practices: a systematic review of trials included within Cochrane systematic reviews*, 15 IMPLEMENTATION SCI., July 2020, at 3 (stating that nudges "have been applied in public health policy to change behaviour and support healthier lifestyle choices").

194. We're bracketing non-welfare harms, discussed elsewhere, and less relevant for an analysis of tangible harms and benefits. *See supra* Part II.B.

195. *See infra* Part VI.B.1–2.

196. *See infra* Part II.B.C.

197. *See supra* Part V.

mentioned above. While half of the initial refusers turned out to be "weak refusers", the other half of the study's cohort continued to utilize the opt-out mechanism.[198] Given that these "strong refusers" dissented twice and had a high level of understanding about the kinds of findings that could be returned to them, it is clear that they have a durable preference not to know genetic information about themselves.[199] When assessing the benefit and harms of this CMN, the question is whether "the potentially significant harms of patients or participants misreporting their preferences on a consent form and forgoing valuable health information outweighs the harms of not respecting the preferences of a handful of strong refusers who do not opt-out."[200]

In this case, economic harms could result from employers or insurers making discriminatory decisions— such as the loss of a job or an inability to acquire affordable health insurance—on the basis of an individual's genetic status.[201] Psychosocial harms might include things like depression, anxiety, and stigmatization.[202] Though there has long been concern about harms associated with genetic testing,[203] these arguments have largely been based on hypothetical concerns and have not been supported by emerging evidence.[204] A comprehensive review of the literature on psychosocial harms associated with genetic testing concluded that current evidence suggests that:

> [T]he original ELSI concerns were unfounded, exaggerated, or, at a minimum, misdirected. At least in the contexts that have been most studied, large negative impacts have not been found in the vast majority of people studied.[205]

A similar story can be told about economic harms, where the Genetic Information Non-discrimination Act (GINA)[206] has served to mitigate most of the concerns about genetic discrimination. Even in other contexts not covered by GINA (such as long-term care and life-insurance), there remains little evidence of widespread discrimination.[207]

198. *See supra* note 106 and accompanying text.

199. *Id.*

200. Berkman, *supra* note 2828, at 5.

201. *Id.* at 60.

202. *Id.* at 56.

203. INST. OF MED., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (Lori B. Andrews et. al. eds., 1994).

204. Berkman, *supra* note 28, at 56–59.

205. *See* Erik Parens & Paul Appelbaum, *On What We Have Learned and Still Need to Learn about the Psychosocial Impacts of Genetic Testing*, 49 HASTINGS CTR. REP. 2, 2 (2019) (introducing a special journal issue devoted to critically analyzing the empirical literature in this field).

206. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110–233, 122 Stat. 881.

207. Yann Joly et al., *Genetic Discrimination and Life Insurance: A Systematic Review of the Evidence*, 11 BMC MED. 25, 35 (2013).

In summary, it appears that there are strong potential direct benefits to the "weak refusers" and somewhat weaker benefits to their relatives. Though there are hypothetical risks to "strong refusers", there is scant evidence in the literature to support these concerns.[208] On net, we argue that the benefits of a CMN in the context of the RNTK generally outweigh the harms. The value of providing some participants with potentially life-saving information is very high, and the burden of depriving a "strong refuser" of an explicit choice is low given that it is possible for them to still opt-out if they feel strongly enough to independently raise the issue with the researchers.

2. Harms to Trust and its Tangible Consequences

A more concerning harm potentially associated with CMNs is that nudging could be viewed as duplicitous, and nudgees' perceptions of being manipulated might erode their trust in medical researchers.[209] Harm to trust is concerning in and of itself but could also have significant tangible consequences when lack of trust in medical research develops into a general lack of trust in medical institutions. The line between medical research and medical care is often blurry, especially because some forms of medical care are only available in research settings, such as experimental drugs for diseases with no known treatment.[210] It can be difficult to distinguish between being treated as a medical research participant and being treated as a patient. As a result, loss of trust in medical researchers may translate to loss in trust in medical institutions more broadly. If CMNs are perceived as duplicitous by undermining nudgees' trust in medical institutions writ large, and if that causes those nudgees to be more hesitant in seeking care and less likely to heed advice from their doctors, it could indirectly contribute to worse health outcomes. This concern could arise for any individual, but it may be particularly salient for members of groups who, because of historical mistreatment, may have less trust and confidence in medical care and research to begin with.[211]

Historical evidence suggests that lack of trust in medical establishments is associated with significantly worse medical outcomes and with health

208. Berkman, *supra* note 28, at 56–60.

209. This analysis applies to feelings of being manipulated or deceived as well as to other psycho-social harms. Donald Wesson et al., *Building Trust in Health Systems to Eliminate Health Disparities,* 322 JAMA 111, 111 (2019). Such feelings are unpleasant in themselves but make it clearly into harm territory when they negatively impact the researcher-participant relationship. Laura Specker Sullivan, *Trust, Risk, and Race in American Medicine*, 50 HASTINGS CTR. REP. 18, 22 (2020).

210. *Clinical Research Versus Medical Treatment*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment (last visited Dec. 10, 2021).

211. Carly Parnitzke Smith, *First, do no harm: institutional betrayal and trust in health care organizations*, 10 J. MULTIDISCIPLINARY HEALTHCARE 133, 140–141 (2017).

disparities.[212] Some medical mistrust is linked to historical medical racism.[213] In addition to past examples of egregious medical misconduct, such as the Tuskegee Syphilis Study,[214] everyday experiences of medical racism are thought to contribute to racialized medical mistrust.[215] Disparities in care and personal experiences of discrimination as well as the general mistrust of social institutions also contribute to medical mistrust.[216] CMNs could exacerbate problems of medical mistrust if they are interpreted as a way for researchers to disrespectfully avoid communication with research participants. To counteract such negative effects, institutions must first take actions to prove themselves worthy of medical trust. Beyond that, efforts to deliberately build trust and increase transparency have proven essential to recruiting populations with a history of research abuse to participate in subsequent medical research.[217] A nudge that appears to mask choice could be perceived as deceptive, and thus potentially in tension with trust-building recommendations.

Worries about medical mistrust are heightened when we have good reason to believe that the CMN concerns a decision that provokes a variety of opinions. In such cases, nudged endorsement of any option is likely to raise suspicions. For example, there is extensive literature on public opinion about sharing newborn blood spots and genomic data. While it is difficult to draw absolute conclusions about public opinion, we do know that people's views on the broad sharing of genomic data are diverse and that there is at least a significant minority of people who have strong views about the acceptability of broad data and sample

212. Wesson et al., *supra* note 209, at 111.

213. *See* LAURA SPECKER SULLIVAN, TRUST, RISK, AND RACE IN AMERICAN MEDICINE, 50 HASTINGS CTR. REP. 18 (2020) (providing an overview of the relationship between racism and trust in the American medical system).

214. *See,* Marcella Alsan et al., *The Tuskegee Study of Untreated Syphilis: A Case Study in Peripheral Trauma with Implications for Health Professionals,* 35 J. GEN. INTERNAL MED. 322, 323 (2019) (discussing medical misconduct that occurred during The Tuskegee Syphilis Study, and its contribution to medical mistrust in the community).

215. Simar Bajaj & Fatima Stanford, *Beyond Tuskegee: Vaccine Distrust and Everyday Racism,* 384 NEW ENG. J. MED. 1,1 (2021).

216. Dwayne Brandon et al., *The Legacy of Tuskegee and Trust in Medical Care: Is Tuskegee Responsible for Race Differences in Mistrust of Medical Care?*, 97 JAMA 951, 951, 954–55 (2005).

217. Monica Skewes et al., *Health Disparities Research with American Indian Communities: The Importance of Trust and Transparency* 66 AM. J. CMTY. PSYCH. 302, 303 (2020).

sharing.[218] Data on views about NBS research is similar.[219] Given the range of perspectives on NBS research and GDS, it is reasonable to exercise caution about endorsing a CMN model.[220] In fact, recognizing the uncertainty in the public polling data, the GDS policy explicitly prohibits an opt-out approach (although as discussed above, the policy does seem to leave room for some strategies that look CMN adjacent).[221] Despite a similarly diverse range of views on the sharing of bloodspots, state-level NBS policies still largely include a CMN approach.[222]

Refraining from CMNs in an effort to improve transparency and build trust might appear to be in tension with the purpose of implementing CMNs to receive the associated benefits. Potential nudgers therefore face a challenge: they must implement CMNs in an effective, yet also transparent and respectful way. The degree to which relevant information must be provided and questions invited will depend on the sensitivity of the choice being masked and the historical levels of distrust among research participant groups—the greater the likelihood of the nudge causing distrust, the greater the need for transparency.[223] For instance, researchers violated the trust of Havasupai Tribe members—who initially consented to participate in a diabetes research study that was expected to generate research benefits—by using their stored blood samples without their consent for genetic testing that discredited cultural creation myths in a way that was deeply offensive to many of the Havasupai.[224] Nudging members of the

218. *See supra* Part I.B.C. One meta-analysis of 51 empirical publications found that strong majorities of people were willing to provide broad one-time consent to have their genomic data shared in a research repository. Nanibaa' A. Garrison, *A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States*, 18 GENET. MED. 663, 666–67 (2016). However, when given a choice between broad, study-specific, or categorical consent, the percentage of people endorsing broad consent dropped significantly. *Id*.; Jodyn Platt et al., *Public Preferences Regarding Informed Consent Models for Participation in Population-based Genomic Research*, 16 GENET. MED. 11, 11, 17, 19 (2014); Tom Tomlinson et al., M*oral Concerns and the Willingness to Donate to a Research Biobank*, 313 JAMA 417, 418 (2015). Some studies even indicate strong support for study-specific consent. David J Kaufman et al., *Public Opinion about the Importance of Privacy in Biobank Research,* 85 AM. J. HUM. GENET. 643, 650 (2009). Confusing matters even more, some studies found majority support for opt-in approaches, but other studies found majority endorsement for opt-out approaches that look closer to CMNs. Garrison, *supra* note 218.

219. One study found that 72% of parents wanted to give specific consent each time their child's bloodspot was going to be used. Daniel Thiel et al., *Community Perspectives on Public Health Biobanking: An Analysis of Community Meetings on the Michigan BioTrust for Health,* 5 J. CMTY. GENETICS 125, 132 (2014). In contrast, a different study found that 55% of parents wanted an opt-out model. Debra Duquette et al., *Michigan BioTrust for Health: public support for using residual dried blood spot samples for health research,* 15 PUB. HEALTH GENOMICS 146, 151 (2012).

220. *See supra* Part II.B.C.

221. *See supra* Part II.C.

222. *See* ASS'N OF STATE AND TERRITORIAL HEALTH OFFS., ISSUE BRIEF: INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH (2015) (showing that most states do not require explicit consent to conduct research with newborn blood spots).

223. Christina M. Pacheco et al., *Moving Forward: Breaking the Cycle of Mistrust between American Indians and Researchers,* 103 AM. J. PUB. HEALTH 2152, 2153 (2013).

224. *Id.* at 2159.

Havasupai Tribe to give blood samples could warrant greater transparency and communication efforts than would be required in nudging the general population of new parents—who have not had such negative experiences with research misconduct—to participate in NBS. Though more transparent nudges might be less effective, the tradeoff would be justified in the aforementioned case. The extent to which perceived duplicity from choice-masking is likely to have harmful consequences depends on past relationships between nudgers and nudgees, as well as the sensitivity of the content of the nudge.

A. Unfair Distribution of CMN Burdens

Another important consideration in evaluating CMNs is whether their burdens are distributed unfairly. CMNs are most likely to impose a burden when participants have difficulty opting out of a default option they would prefer not to receive.[225] This unfair distribution of resistibility may occur at the individual or the group level. On the individual level, it would be unfair to impose an extreme burden on a research participant solely for the purpose of lessening a benefit to others.[226] Nudges can be considered unfairly distributed on the group level when the individual characteristics that make resisting nudges difficult fall along group lines or are related to group membership.[227] Unfair distribution of nudging effects along group lines is especially concerning because it has the potential to exacerbate underlying social injustices, particularly if the distribution disadvantages already disadvantaged groups. If it is harder for some nudgees to resist a nudge than others, it would be especially unfair if those who had the most difficulty resisting the nudge also belong to a disadvantaged group in society.[228]

There are two reasons we might worry about unfairly distributing nudge burdens along group lines. First, nudges could concentrate burdens or harms in certain groups without providing benefits to members of the same group. This might be the case, for example, if a CMN—today—nudged members of the Havasupai Tribe to donate genetic samples to be used in research unlikely to benefit the donors.[229] Given historical conflicts, such a nudge could do serious damage to group trust in medical institutions. Second, CMNs might be less resistible to some groups than to others. Even if opt-out mechanisms are easy and readily available, the nature of the CMN requires that participants self-

225. *See infra* Part VI.C.

226. *See, e.g.,* JUDITH JARVIS THOMPSON, THE REALM OF RIGHTS 135 (1992); *See* SCANLON, *supra* note 109, at 235 (arguing that one should be saved from serious pain and injury at the cost of inconveniencing others or interfering with their amusement).

227. *See* Daniel Hausman*, Protecting Groups from Genetic Research,* 22 BIOETHICS 157, 159 (2008) (describing group harms as something that individuals face because of their group membership).

228. JOHN RAWLS, A THEORY OF JUSTICE 75, 75–78 (1971) (discussing the similar idea that inequalities should bring the most benefits to the least advantaged members of society, in context of his difference principle).

229. *See* Pacheco et al., *supra* note 223223, at 2154 (providing an overview of the Havasupai case).

identify as choosing to opt-out of it.[230] The option is only available to those who actively select it, which involves articulating one's preferences, seemingly contradicting the research team's preferences.[231] Members of groups with cultural values that emphasize deference to authority, groups with low literacy, or members of groups that are generally socially vulnerable may feel less confident in articulating their concerns or desire to activate the opt-out process.

At the same time, it is important to ask why individuals might want to resist a given nudge. Members of groups who have difficulty resisting a nudge may also have more to lose from resisting. For example, in a recent paper, Mrkva and colleagues suggest that well-implemented nudges can be used to *reduce* choice disparities.[232] Through a series of studies, they show that individuals with low-socioeconomic status were more impacted by nudges than those with high-socioeconomic status, and that individuals with lower levels of domain knowledge and numeracy were more impacted by nudges than individuals with high levels of domain knowledge and numeracy.[233] These findings suggest that carefully constructed nudges that benefit low-socioeconomic status individuals help to reduce inequalities and promote equity. If the nudge is legitimate and beneficial overall, it might be more unfair not to nudge than it would be to nudge. This consideration might depend, to some extent, on whether the nudge is paternalistic or justified by appealing to society, generally. Means-paternalistic nudges are designed to offset potential disproportionate burdens with benefits to the nudgees on their own terms.[234] Thus, it is more important that nudges justified by their contribution to the social good are shown to not be unfair than it is for means-paternalistic nudges that promote a nudgee's own interests.[235] At any rate, nudgers must be especially aware that individuals belonging to vulnerable social groups may be less likely to self-identify as having non-default preferences and should, as a result, avoid designing nudges that would take advantage of that dynamic.

B. Lack of Ethically Superior Feasible Alternatives

Instances of paternalism—even justified and resistible ones, as any nudge that satisfies the three considerations listed above will be—should be taken seriously since they involve acting on behalf of other people. Nudges are intended to be effective and should therefore, at least to some degree, restrict the

230. *See infra* Part VI.C.

231. *Why an opt-out rather than an opt-in or consent?,* UNDERSTANDING PATIENT DATA, https://understandingpatientdata.org.uk/news/why-an-opt-out (last visited Dec. 10, 2021).

232. Kellen Mrvka et al., *Do Nudges Reduce Disparities? Choice Architecture Compensates for Low Consumer Knowledge,* 85 J. OF MKTG. 67, 80–81 (2021).

233. *Id.* at 73.

234. *See supra* Part III.

235. *See supra* Part III.

nudgee's scope of self-determination. To justify the use of a CMN, the researcher must show that there are not feasible effective alternatives to achieve a nudge's given aim.[236] While comparison with feasible alternatives must ultimately be done on a case-by-case basis, cognitive biases are strong indicators of a lack of feasible alternatives.

1. Counteracting Cognitive Biases

Nudges will often be the best feasible way to achieve a desired outcome when they address decisions in which choosers are likely to be affected by cognitive biases because cognitive biases often prevent people from rationally pursuing what they would prefer in light of their considered beliefs, attitudes, and preferences. In a decision that requires careful deliberation, someone might display cognitive bias by becoming frustrated and choosing rashly without attempting to consider all available options; nudges can counteract that effect. Not all kinds of choices are equally subject to cognitive biases. Typically, the greater the likelihood of a decision inducing cognitive bias, the more justified a nudge will be.[237] The emotionally charged nature of medical decision-making is likely to contribute to cognitive bias.[238] A decision-maker's emotions often affects her choice, particularly if the choice will have effects far into the future.[239] Research has shown, for example, that when choosers feel stressed by the decision they are asked to make, they tend to unwittingly overestimate how long they will feel that way and decide differently than they would in a calmer state.[240] What is at stake in a particular decision also has implications for how much cognitive bias is likely to enter into the choice. It has been suggested that in very low stakes decisions, choosers might experience low processing motivation and consequently select the most convenient option without careful consideration.[241] At the same time, very high stakes decisions might also induce cognitive bias because they can be overwhelming and make reasonable deliberation very

236. Perhaps the most common objection to CMNs is to ask why individuals should be nudged into making better choices instead of being educated and enabled to make better choices for themselves. While education might promote autonomy more than nudging, that kind of education is not always effective or feasible. *See supra* Part V.

237. Bart Engelen, *Nudging and rationality: What is there to worry?*, 31 RATIONALITY AND SOC'Y 204, 205 (2019) (explaining how nudges tap into heuristics and biases).

238. Pat Croskerry, *From Mindless to Mindful Practice—Cognitive Bias and Clinical Decision Making*, 368 N. ENGL. J. MED. 2445, 2447 (2013).

239. George Lowenstein & Jennifer S. Lerner, *The Role of Affect in Decision Making*, *in* HANDBOOK OF AFFECTIVE SCIENCES 619–21 (R.J. Davidson, K.R. Scherer & H.H. Goldsmith eds., 2003).

240. *See, e.g.,* George Loewenstein, *Hot–Cold Empathy Gaps and Medical Decision Making,* 24 HEALTH PSYCH. 49, 59 (2005) (discussing how individuals have difficulty estimating their own behavior and preferences across affective states).

241. Engelen, *supra* note 5, at 55.

difficult.[242] Nudges are more likely to outperform feasible alternatives in highly emotionally charged situations and when decision stakes are particularly high or low.[243]

Returning to our cases, an excellent example of cognitive biases can be found in the RNTK debate. There is extensive psychological literature about individuals' poor ability to predict how future negative events will impact our emotional wellbeing.[244] This affective forecasting literature suggests that while people think that future unfortunate events will be devastating, most humans are actually more emotionally resilient than we realize and we have the ability to adapt to even terrible news.[245] This is particularly true in the context of genetic testing, where most reactions to unfavorable information are mild and transient.[246] This kind of widespread cognitive bias might be used to support implementation of a CMN. In contrast, consider the cognitive biases inherent in the way that consent is obtained for NBS. The typical procedure is to ask new parents, in the days after giving birth, to review a stack of paperwork, including the notification that they can opt out of allowing their child's bloodspot to be used for future research.[247] This chaotic time might not be an ideal moment to implement a CMN because the parents' ability to cognitively engage and deliberate might be compromised.

2. Least Restrictive Alternative

Stakes and emotional valence can, at best, give a rough indication of whether a CMN is likely to be better than feasible alternatives, however. To make that determination in specific cases, it is necessary to directly compare alternatives in terms of their relative harms and benefits. This comparison can be done with the widely used less restrictive alternatives (LRA) test, which compares a proposal to alternatives along two dimensions: restrictiveness and

242. Monica E. Lemmon & Peter A. Ubel, *In Defense of Nudging When the Stakes Are High*, 19 AM. J. BIOETHICS 62, 62–63 (2019).

243. *Id.*

244. *See, e.g.*, Elisabeth W. Dunn & Simon M. Laham, *Affective Forecasting: A User's Guide to Emotional Time Travel*, *in* AFFECT IN SOCIAL THINKING AND BEHAVIOR 177, 177–178 (Joseph P. Forgas ed., 2006); Timothy D. Wilson & Daniel T. Gilbert, *Affective Forecasting*, *in* 35 ADVANCES IN EXPERIMENTAL SOCIAL PSYCH. 345, 346, 401 (James M. Olson & Mark P. Zanna eds., 2003) (discussing impact bias's effect on one's ability to accurately predict how future events will impact one's wellbeing).

245. *Id.*

246. *See* S.A. Peters et al., *The Future in Clinical Genetics: Affective Forecasting Biases in Patient and Clinician Decision Making*, 85 CLINICAL GENETICS 312, 313–14 (2014) (discussing research showing that individuals overestimate the negativity of psychological outcomes of predictive genetic testing); *see also* Marita Broadstock et al., *Psychological Consequences of Predictive Genetics Testing: A Systematic Review*, EUR. J. HUM. GENETICS 731, 731, 735 (2000) (reporting studies showing no evidence of high levels of, nor increases in, emotional distress after predictive genetic testing).

247. *See supra* Part I.B.

effectiveness.[248] In the case of CMNs, restrictiveness measures how harmful the nudge would likely be and effectiveness measures how likely it is to achieve its aims.[249] The test is easy to use when one alternative is dominant—meaning that it is both more effective and less restrictive. When no alternative under comparison is superior on both axes—such as when the nudge is more effective but slightly more restrictive—there is no shortcut to careful deliberation and weighing of alternatives. Restrictiveness should only be tolerated if the effectiveness is far greater, but harms to autonomy and social justice put a limit on the level of restrictiveness that can be tolerated.

To illustrate this kind of analysis, consider different alternatives to a CMN in the context of the RNTK. As one alternative, investigators could include more detail in the consent form about the kinds of secondary findings that might be discovered, thinking that this could increase understanding. Such a proposition would have to be tested, however, because there is extensive literature that calls into question participants' ability to engage with and internalize basic concepts being conveyed in consent forms.[250] Another alternative might be to schedule a dedicated conversation with a genetics counselor about the RNTK. However, this would be prohibitively resource intensive and might not even be feasible given the well-documented shortage of genetic counselors.[251] A final option would be to recontact participants who refused secondary findings to give them another chance to make a choice. This option, however, risks alerting those who really did not want to know about the existence of a positive secondary finding. Given these options, it seems reasonable to conclude that a CMN is the best option, assuming that there is a mechanism for self-identified refusers to easily opt-out.

An analysis of LRAs becomes more complicated in situations where there is only societal benefit—like the NBS and GDS cases—involving a two-step assessment of how much scientific value is lost when you switch from a CMN to an explicit opt-out mechanism. This will first typically require an empirical analysis of the difference in size and composition of the research resource under a CMN and other consent strategies. For instance, how many fewer people (and which ones) will not agree to give their sample for future research if explicitly asked? It then becomes important to ask whether that lost value significantly undermines the research goals. For example, if researchers want to create a genomic database to study common conditions, losing a small portion of a

248. C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law,* 116 COLUM. L. REV. 927, 929 (2016).

249. *Id.*

250. *See* Amulya Mandava et al., *The Quality of Informed Consent: Mapping the Landscape. A Review of Empirical Data from Developing and Developed Countries*, 38 J. MED. ETHICS 356, 356–57 (2012) (discussing reasons why some patients have difficulty understanding concepts conveyed in consent forms, such as lack of formal education and experience with biomedical research and consent procedures).

251. *See* NAT'L SOC'Y OF GENETIC COUNS., 2021 PROFESSIONAL STATUS SURVEY: EXECUTIVE SUMMARY (2021) (illustrating that there are many states with just a few genetic counselors).

repository might not be deleterious unless those losses came from a group of particular interest. A research resource being used to study rare diseases or variants might have more scientific justification to maximize the size and representativeness of the repository.

VII. CONCLUSION

Effective use of CMNs in medical research has the potential to benefit individuals in ways they themselves endorse, to help people collectively, and to promote important social objectives.[252] For the kind of purely informational nudges we are concerned with here, the benefits extend beyond the individuals being nudged; our basis for justifying CMNs thus extends beyond individuals to consider collective and societal benefit. As our examples of the RNTK genetic information about oneself, NBS, and GDS all show, these benefits are not merely hypothetical.[253] But neither are their costs. While CMNs have great potential positive effects, they could also transgress individuals' autonomy interests. If medical researchers are to use CMNs, it is important that they do so in legally and ethically acceptable ways. Thus, the challenge facing researchers is to design nudges that are likely to be effective overall, but that are also easily resistible *to those who wish to resist.*[254] Where the sweet spot is when soliciting questions without raising concerns will depend on the context of a particular nudge. The primary aim of this paper has been to provide a framework for designing acceptable CMNs that capture the potential benefits without incurring the potential costs.

Our analysis of the reasonable person standard and United States federal research regulations shows how CMNs fit into current legal regulations.[255] Research regulations require medical researchers to provide participants with enough information so that participants understand the research they intend to participate in, but do not require explicit choice.[256] Importantly, they refer to the reasonable person standard to determine what counts as sufficient.[257] The structure of the RPS helps us see *how* reasonableness is evaluated by directing us to consider all relevant considerations and weigh them in a reasonable way.[258] For the medical research questions that we are interested in, a reasonable person would weigh her interests in having a full range of choices explicitly presented against how both she and others are likely to be affected by the nudge. CMNs

252. *See supra* Part V.

253. *See supra* Part II.

254. *See supra* Part III.

255. *See supra* Part IV.

256. Umesh Chandra Gupta, *Informed consent in clinical research: Revisiting few concepts and areas*, 4 PERSPS. IN CLINICAL RSCH. 26, 27 (2013).

257. Mazur, supra note 94.

258. *Id.*

that respect protected autonomy domains and conform to the considerations discussed in Part VI of this article are expected to be acceptable to reasonable persons.[259]

We expect legally and ethically acceptable CMNs to have legitimate policy aims, generate more benefits than harms, not unfairly distribute burdens, and lack feasible alternatives. The stringency of our acceptability considerations, however, will vary with the context. In some cases, historical facts might make a certain choice particularly sensitive and render masking inappropriate,[260] Moreover, significantly more masking may be acceptable when benefits are likely to accrue directly to the individual being nudged. There is precedent for this kind of sliding scale of acceptability.[261] Our acceptability considerations for CMNs are similarly responsive to the social and historical context of the choice, the directness of the (positive and negative) consequences likely to accrue to research participants, and the degree of ethical controversy surrounding the nudge. Return once more to the RNTK example. While a nudge toward receiving medically actionable secondary findings would likely be appropriate in *most* contexts, it would not be in *all* contexts.[262]

The most likely challenges to CMNs come from critics who claim that CMNs are likely to violate fundamental autonomy interests. While we acknowledge that CMNs may not be welcome on every view of autonomy, they are compatible with the most important features of autonomy; nudged research participants can still be the driving forces of their own lives. The easy resistibility built in to acceptable CMNs undermines objections that CMNs would force research participants into unwillingly and unwittingly accepting researchers' default decisions. Medical research is complicated and can be difficult for participants to understand; thoughtfully designed CMNs have an important role to play in gently helping large numbers of research participants reach decision outcomes that really are best for them and their communities.

259. *See supra* Part VI.

260. *See supra* Part VI.B.2–V.C.

261. *See, e.g.,* Mathews v. Eldridge, 424 U.S. 319, 335 (1976) (holding that resolution of due process "requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and probable value, if any, of additional or substitute procedural safeguards; and the Government's interest, including the functions involved and the fiscal and administrative burdens that the additional or substitute procedures would entail"). Consider, as an analogy, how numerous court rulings have asserted that the requirements of due process vary with context and respond to a complex set of the individuals' interests likely to be affected, the government's legitimate interests in its official action, and risks of likely harms to those interests. *Id.*

262. Pacheco et al., *supra* note 223. For research with communities who have previously had their genetic information used in ways they neither consented nor approved of, such as the Havasupai people in Arizona, such a nudge could be perceived as disrespectful or insensitive, and strain researcher-community relationships. *Id.* at 2154.