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Disclosing Privacy and Discrimination Protections in Informed Consent

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DISCLOSING PRIVACY AND DISCRIMINATION PROTECTIONS IN INFORMED CONSENT

Anya E.R. Prince†

ABSTRACT

Recent empirical work shows that providing greater detail about limitations of genetic anti-discrimination protections in informed consent documents is likely to lower individuals' willingness to participate in research studies. This article presents these empirical findings and analyzes the implications of the findings for clinical care and for privacy and discrimination risks beyond genetic discrimination. While the paper argues that further research is needed to fully understand the potential implications of disclosure of legal protections in the clinical setting, there are clear implications in the research setting. Since individuals are likely to alter their decision to participate in research based on the depth of information provided, informed consent should contain detailed information about privacy and discrimination risks. However, for participants to truly understand the risk of loss of privacy and potential for discrimination that flows from information disclosures in research, they arguably must have a robust understanding of both when and how information may be shared, but also the legal protections and limitations that govern use of that data. Now, more than ever, it is essential to understand the privacy risks associated with

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joining a study since research trends related to big data and secondary research are vastly increasing the privacy risks for participants. Yet, while it is easy to state that individuals should be told of both privacy and anti-discrimination laws and their respective limitations, disclosing these in practice is much more complex. For every law, there are countless limitations that could be enumerated, but such disclosures would quickly make informed consent unwieldy and counterproductive. Thus, this paper argues that institutional review boards (“IRBs”) can help to find a limiting principle to the disclosures by assessing the likelihood of harm and contextualizing the risks to the study population. This will balance between over- and under-disclosure of legal protections and limitations while still fulfilling important foundational goals of informed consent.

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I. INTRODUCTION

Informed consent is a foundational ethical and legal principle in both human subjects research and clinical care. It is grounded in the ethical principle of respect for autonomy—the belief that people should be “free to choose and act without controlling constraints imposed by others”.¹ The vital importance of informed consent is generally not questioned. However, there is greater debate over what and how much information must be disclosed to meet the ethical goals and legal requirements of consent.² In the research setting, the Common Rule—federal regulations setting the parameters for human subjects research—dictates that researchers must disclose “information that a reasonable person would want to have in order to make an informed decision about whether to participate . . .”.³ Specifically, one of the basic elements of informed consent is “a description of any reasonably

1. RUTH R. FADEN & TOM BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 8 (Oxford Univ. Press. 1986).

2. Christine Grady, *Enduring and Emerging Challenges of Informed Consent*, 372 *NEW ENG. J. OF MED.* 855, 855 (2015).

3. 45 C.F.R. § 46.116(a)(4) (2018).

foreseeable risks or discomforts to the subject”.⁴ Traditionally, the most likely risks were medical, such as a complication from a procedure or a side effect of a pharmaceutical in a clinical trial.

However, informed consent doctrine increasingly recognizes the importance of disclosing non-medical information, including non-medical risks, such as privacy and discrimination risks. Additionally, new trends in research challenge the baseline of only returning medically-related information as non-medical information becomes increasingly relevant to autonomous decision-making.⁵ Notably, there is an increasing collection of large-scale behavioral or genomic data, blurring bounds between research and clinical care, and preservation of individual data for secondary research. For example, in genomic research the physical risk of participation in the study is often no more than a blood draw. Instead, the primary foreseeable risks to participation are privacy-related risks, such as loss of confidentiality, risk of discrimination, or misuse of personal data.

The question becomes how much detail researchers should provide to individuals about privacy risks and subsequent potential for discrimination, including how much information about legal protections is needed to fully understand privacy and discrimination risks. On the one hand, it is foreseeable that a reasonable participant would want to know about potential privacy risks, the applicable legal protections that protect their data or the misuse of their data, and potential gaps in coverage. However, even identifying what information to provide could involve complex legal analysis implicating issues of state/federal preemption, choice of law, and legal interpretation depending on the context. This analysis is surely outside the expertise and scope of practice of most people obtaining informed consent from individuals.

Yet, it is also recognized that some information about both legal protections and gaps in protections can be relevant to individuals to understand potential risks of joining a study and

4. 45 C.F.R. § 46.116(b)(2) (2018).

5. Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 UNIV. ILL. L. REV. 821, 828 (2015); Judith F. Daar, *Informed Consent: Defining Limits through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 195 (1995).

thus necessary for valid informed consent. For example, the Office of Human Research Protections (OHRP) in the U.S. Department of Health and Human Services has provided guidance about describing the protections of the Genetic Information Nondiscrimination Act (GINA) to prospective participants of studies collecting genetic information, noting that participants should be told of both legal protections *and* limitations.⁶

As with all laws, there is a seemingly endless list of scenarios that GINA does not extend to. For example, while GINA protects against genetic discrimination in health insurance and employment, it does not cover life insurance—or, for that matter, educational facilities and mortgage companies. Given this, what is the limiting principle regarding disclosure of information about privacy laws and anti-discrimination protections? On the one hand, since it is foreseeable that a reasonable person would want to know about the full extent of protections, it is important to include nuanced information in the consent document. On the other hand, informed consent documents cannot practically be expected to include all information about all potential limitations of protections and associated risks. As an early seminal case on informed consent in the clinical setting describes:

At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risks by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain

6. U.S. DEP'T HEALTH & HUM. SERV.: OFFICE FOR HUM. RSCH. PROTECTIONS, GUIDANCE ON THE GENETIC INFORMATION NONDISCRIMINATION ACT: IMPLICATIONS FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS (Mar. 24, 2009), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html> [<https://perma.cc/BQ3M-JFQN>] [hereinafter OHRP Guidance].

cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.⁷

While this quote is discussing medical risks in the clinical setting, it is no less relevant when thinking about non-medical risks in the research setting. Two important themes come to the fore from this quote: first, risks that are minimal may not need to be disclosed and second, that disclosing risks may increase apprehension in the consenting individual. These themes are equally relevant in the context of disclosing privacy and anti-discrimination protections, where disclosing detailed information about legal limitations could heighten fear of discrimination, but where quantifying the likelihood of harm can be difficult given many privacy violations are dignitary harms and there may be limited evidence of past discrimination.

Using the example of disclosing the genetic anti-discrimination protections of GINA and its gaps, this Article proceeds in seven parts. Section II briefly details the basic contours of informed consent, with a focus on the need to disclose reasonably foreseeable risks to individuals. Recently, there has been a growing recognition of the need to disclose both medical risks and non-medical risks, such as potential privacy harms.

To explore such disclosures in greater depth, Section III presents data from an empirical survey exploring whether and how informed consent language related to legal anti-discrimination protections affects individuals' willingness to participate in a hypothetical genomic study and concerns of genetic discrimination. Overall, the empirical research shows that providing individuals with greater information about the gaps in legal protections is associated with a lower willingness to participate in the proposed study and a heightened concern for future genetic discrimination.

Sections IV and V explore the potential implications of these findings for both clinical care and research respectively. Due to key differences between informed consent in research and clinical care, this paper argues that more data is needed to fully understand the potential implications in the clinical setting.

7. *Salgo v. Leland Stanford Jr. Univ. Bd. of Tr.*, 154 Cal. App. 2d 560, 578 (1957).

However, there are clear implications that individuals consenting to research are likely to find many types of privacy and discrimination risks, and their associated legal protections, relevant to their choice whether to join a research study. This indicates that informed consent in research may need to disclose more than it currently does about privacy and discrimination risks, especially as it relates to limitations of current legal protections.

Section VI analyzes the complexities of disclosing privacy and discrimination risks in practice. If we take seriously the proposition that reasonable participants will find detailed information about legal limitations relevant to their decision to join a study, then many current informed consent documents likely under-disclose legal protections and their limitations. However, too much information in informed consent also threatens the goals of participant understanding. One way to create a limiting principle is to contextualize the risk information and legal protections to the participant so that extraneous information is not included, but this raises many complexities and concerns about expertise. Instead, this paper argues that privacy and discrimination protections and limitations should be assessed and contextualized at the level of the study population. This will allow research participants to be told of a broad range of foreseeable privacy and discrimination risks associated with the study that are likely relevant to a reasonable participant, thus fulfilling important goals of informed consent. Section VII briefly concludes.

II. INFORMED CONSENT & REASONABLY FORESEEABLE RISKS

Informed consent is a foundational requirement in both clinical care and research. While there are many facets of informed consent, it can be broadly defined through the following criteria delineated by Faden and Beauchamp: “1) a patient or subject must *agree* to an intervention based on an *understanding* of (usually disclosed) relevant *information*, 2) consent must *not be controlled* by influences that would engineer the outcome, and

3) the consent must involve the intentional giving of *permission* for an intervention.”⁸

In the research setting, the relevancy of the information to be disclosed is measured by what a reasonable person would want to know.⁹ However, the bounds of what must be disclosed during informed consent is often difficult to define.¹⁰ The Common Rule lays out nine ‘basic elements’ of informed consent for research.¹¹ Informed consent must include a description of: 1) the purpose and procedures of the proposed research; 2) reasonably foreseeable risks; 3) reasonably expected benefits; 4) alternative procedures or courses of treatment; 5) confidentiality protections; 6) available compensation and recourse if injury occurs; 7) contact information for follow-up questions; 8) the voluntary nature of the study; and 9) when applicable, potential future studies with deidentified biospecimens.¹²

While there are many potential categories of key information that ought to be disclosed to individuals, a consistent theme is that individuals must be informed of the foreseeable risks. Historically, disclosures of foreseeable risks were likely to be about medical risks associated with the procedure or study, such as a complication from surgery or potential side effects of a drug. Indeed, in the clinical context, some legal informed consent requirements, at both common law and in state statutes, specifically narrow the discussion of risks to the medical realm.¹³ For example, the New Jersey Bill of Rights for Hospital Patients, states that individuals have the right to receive information

8. FADEN & BEAUCHAMP, *supra* note 1, at 54 (emphasis in the original).

9. *See infra* Section IV.A.2.

10. *See, e.g.*, Sawicki, *supra* note 5, at 828 (noting that “ethical theories of informed consent rarely provide specific guidance about the substantive information that ought to be disclosed as part of the consent process”).

11. 45 C.F.R. § 46.116(b) (2018). This list comes from the 2019 version of Common Rule, referred to as the revised Common Rule. *See infra* Section V.B.

12. 45 C.F.R. § 46.116(b) (2018); *see also* 45 C.F.R. § 46.116(c) (2018) (listing “additional elements of informed consent” that should also be included when appropriate).

13. Sawicki, *supra* note 5, at 832.

necessary to give informed consent, including ‘medically significant risks’.¹⁴

However, there has been increasing recognition of the need to expand the scope of discussions to risks beyond just medical, such as financial or legal risks.¹⁵ In part, this shift is necessary because “the ethical principles of decisional autonomy that underlie informed consent demand a broader understanding of materiality.”¹⁶ While there have been calls for broadening disclosures in the clinical realm,¹⁷ this expansion has been more often incorporated into informed consent policies in the research realm. For example, New Jersey’s research-related informed consent statute, unlike its clinical-related statute described above,

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14. N.J. Stat. Ann. § 26:2H-12.8 (2019).
 15. *See generally* Sawicki, *supra* note 5 (cataloging types of nonmedical information that patients could consider relevant to clinical care, including provider-specific characteristics and patients’ nonmedical interests, such as financial concerns or maintaining privacy); *see also* OHRP Guidance, *supra* note 6. This trajectory from medical to broader information mirrors changes in informed consent disclosures beyond only the risks involved. *See generally* Sawicki, *supra* note 5. For example, there has been discussion over whether physicians or researchers should be required to disclose financial interests during informed consent. *Id.* at 823–24. The financial implications of research were also topics of debates given high profile cases. *See Moore v. Regents Univ. Cal.*, 793 P.2d 479 (Cal. 1990). Subsequently, the revised Common Rule has added a requirement that consent documents include a statement of the potential that biospecimens could be used for commercial profit and whether research participants will share this profit. 45 C.F.R. § 46.116(c)(7) (2018).
 16. Sawicki, *supra* note 5, at 826.
 17. *Id.* at 821 (arguing that non-medical information should be disclosed to patients during informed consent when it is within the physician’s knowledge and expertise and would be material to a reasonable patient); *see also* Ashley H. Wiltbank, *Informed Consent and Physician Inexperience: A Prescriptive for Liability*, 42 WILLIAMETTE L. REV. 563, 565–66 (2006) (discussing trends in case law requiring disclosure of physician inexperience with a particular procedure during informed consent); Laurel R. Hanson, *Informed Consent and the Scope of a Physician’s Duty of Disclosure*, 77 NORTH DAKOTA L. REV. 71 (2001) (exploring when a physician may need to disclose information about personal factors, such as drug or alcohol use or medical condition, or about financial interests).

does not cabin the risks to medical ones, but instead requires documents to detail “any attendant discomfort and reasonably foreseeable risks to the subject.”¹⁸

The expansion of recommended disclosures stands to reason because the focus on purely medical information during informed consent does not reflect how the lay public may conceptualize decision-making and relevant information.¹⁹ For example, in 1997, soon after the discovery of *BRCA1*, a gene associated with an increased risk of breast and ovarian cancer, a qualitative study assessed what information women would want to know prior to undergoing genetic testing for cancer risk.²⁰ The women in the study indicated they would want to know about risks, including “the possibility of false negatives and positives, a false sense of security after a negative results, anxiety, guilt, stigmatization, and discrimination.”²¹ This expansive view of risks an individual may want to know about before making a decision to undergo a procedure or join a research study is not surprising given individual interests and values.²²

III. EXAMPLE: DISCLOSING GENETIC DISCRIMINATION PROTECTIONS

Informed consent is meant to provide individuals with sufficient information about a research study to allow them to understand key details of participation and make an autonomous choice regarding participation. These disclosures must include information about reasonably foreseeable risks of participating in a research venture, including, it is increasingly argued, potential non-medical risks associated with involvement.²³ Yet, the mere act of declaring that non-medical risks should be disclosed does not make the process simple. The determination of what

18. N.J. REV. STAT. ANN. § 26:14-4 (2021).

19. Sawicki, *supra* note 5, at 821.

20. Barbara A. Bernhardt et al., *Toward a Model Informed Consent Process for BRCA1 Testing: A Qualitative Assessment of Women’s Attitudes*, 6 J. GENETIC COUNSELING 207, 207 (1997).

21. *Id.* at 219.

22. Sawicki, *supra* note 5, at 821; Daar, *supra* note 5.

23. *See infra* Section II.

information should be included within the category of reasonably foreseeable risks and the level of detail within these disclosures is a complex and thorny process.

Here it is helpful to think about a concrete example in order to ground the remaining discussion of disclosing non-medical risks, specifically those related to privacy and discrimination, in informed consent. A poignant example is how researchers should approach disclosure of the foreseeable risk of genetic discrimination that could arise out of participation in research studies that include genetic testing or sequencing. Genetic discrimination in this context is the concern that research participants could face future adverse consequences, such as in employment or insurance, based on the genetic information that is discovered, collected, or processed during the research.

A key element regarding disclosure of potential risks of genetic discrimination following participation in a research study is discussion of the relevant federal legal protection in this area, GINA.²⁴ GINA prohibits health insurers and employers covered by the act from discriminating against an individual based upon genetic information, including genetic test results.²⁵ However, the law does not completely eliminate foreseeable risks of genetic discrimination following research participation due to the law's narrow focus on employment and health insurance.²⁶

A. Current Practices In Disclosure of GINA

The OHRP has model language for researchers to discuss GINA's protections in informed consent.²⁷ The guidance notes the important protections of GINA, but warns that "descriptions of the reasonably foreseeable risks of genetic research . . . do not

24. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified as amended in scattered sections of 26, 29, and 42 U.S.C.).

25. *Id.*

26. Andrea Lenartz et al., *The Persistent Lack of Knowledge and Misunderstanding of the Genetic Information Nondiscrimination Act (GINA) More than a Decade After Passage*, 12 GENETICS MED. 2324, 2324 (2021) (noting that GINA has some important gaps, since it does not cover life, long-term care, or disability insurers).

27. OHRP Guidance, *supra* note 6.

overstate the protections provided by GINA.”²⁸ They specifically note that, while GINA prohibits discrimination by covered health insurers and employers, it does not regulate life, long-term care, or disability insurance and does not apply to employers with fewer than fifteen employees.²⁹

As the OHRP guidance makes clear, it is seen as necessary to disclose both legal protections *and* limitations.³⁰ However, in this instance, the guidance only highlights four specific gaps in the law—lack of coverage for life, long-term care, and disability insurance and the limitation to only employers with more than 15 employees.³¹ It does not discuss the myriad of other entities that are not covered within GINA’s purview, such as property or casualty insurers, mortgage lenders, educational institutions, the military, or law enforcement, even though there has been societal debate over or evidence of use of genetic information by each of these entities.³²

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *See, e.g.*, Mark A. Rothstein & Laura Rothstein, *How Genetics Might Affect Real Property Rights: Currents in Contemporary Bioethics*, 44 J. L. MED. & ETHICS 216, 216 (2016) (discussing the potential ways that genetic information could be used in real property, including mortgage insurance); *Chadam v. Palo Alto Unified School District*, 666 Fed. App’x 615, 616 (9th Cir. 2016) (deciding motions related to a case alleging that a child was discriminating against, in violation of the Americans with Disabilities Act (ADA), because he carried a genetic marker for cystic fibrosis and was assigned to a different school after his middle school learned of this medical information); Susannah Baruch & Kathy Hudson, *Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World*, 83 AM. J. HUM. GENETICS 435, 439–41 (2008) (analyzing genetic nondiscrimination policies and gaps in protection in military genetics); Natalie Ram, *Genetic Privacy After Carpenter*, 105 VA. L. REV. 1357, 1357 (2019) (discussing law enforcement use of genetic information). The guidance also does not discuss several exceptions within GINA that allow employers and health insurers to collect genetic information in limited circumstances, such as when an employee requests family or medical leave or as part of a voluntary wellness program. 42 U.S.C.A. § 2000ff-1 (2008). Employers or health insurers who collect this genetic information still could not use the information

As a result of this guidance, many genomic research studies have incorporated this or similar language into their informed consent documents.³³ For example, a review of model informed consent forms publicly available by IRBs at 38 colleges and universities, shows that 26 included at least some information about GINA on relevant forms.³⁴ Of those that mention GINA, most (24) follow OHRP guidelines and discuss both GINA's coverage of health insurance and employment, as well as its gap regarding life, long-term care, and disability insurance. A handful (6) mention state law variations of GINA, including additional protections or gaps. Nine noted that GINA does not provide protection for manifested conditions. However, only one

to discriminate against an individual; however, the exceptions do increase risks of privacy and discrimination violations at least slightly.

33. See, e.g., *CSEER Research Materials*, CLINICAL SEQUENCING EVIDENCE-GENERATING RSCH., <https://cser-consortium.org/cser-research-materials> [<https://perma.cc/3DNQ-4EHV>] (last visited Oct. 30, 2022); Gail E. Henderson et al., *The Challenge of Informed Consent and Return of Results in Translational Genomics: Empirical Analysis and Recommendations*, 42 J. L. MED. & ETHICS 344, 351 (2014); Laura M. Beskow et al., *Sample Consent Document 3: The Electronic Medical Records and Genomics (eMERGE) Network Consent & Community Consultation Workgroup Informed Consent Task Force*, NAT'L HUM. GENOME RSCH. INST. (Dec. 15, 2009), https://www.genome.gov/sites/default/files/media/files/2022-01/eMERGE_consent.pdf [<https://perma.cc/KGZ2-UD6Y>].
34. These statistics were gathered by the author, A.E.R.P. and a research assistant. The colleges and universities were chosen following methodology from Devon Check and colleagues. Devon K. Check et al., *Certificates of Confidentiality and Informed Consent: Perspectives of IRB Chairs and Institutional Legal Counsel*, 36 IRB 1, 2 (2014). Like Check, Prince and research assistants identified the US institutions with both a medical school accredited by the American Association of Medical Colleges and a school of public health accredited by the Association of Schools of Public Health. We identified 43 institutions. We then searched model consent forms on the institutions' IRB websites for discussion of GINA, its protections, and its limitations. Five institutions had consent forms that were unavailable to the general public and were not included in our counts. Thus, we reviewed consent forms from a total of thirty-eight universities. Underlying data is available upon request.

mentioned additional gaps in GINA, specifically the lack of full coverage within the military context.

Many of the reviewed informed consent standard forms coalesce around the OHRP guidelines. However, this does not mean that experts necessarily agree that this is the level of information that should be provided. In 2015, Laura Beskow and colleagues published a Delphi study seeking expert consensus regarding the necessary information participants must have ‘adequate comprehension’ about prior to joining a study.³⁵ They found that experts could not agree as to what level of detail about GINA was necessary for participants to understand. Experts were split as to whether they believed that participants did not need to understand anything about GINA or that they needed to understand that “there is a law against discrimination based on my information[.]”³⁶ Approximately a quarter of the experts felt that these options failed to disclose enough about GINA, in part because they did not discuss the limitations of the law.³⁷ As debate continues regarding the level of detail about GINA necessary to include in informed consent documents, a recent empirical study, presented below, sheds light on how discussion of limitations of GINA may impact participants.

B. Empirical Study

Should such legal limitations that increase privacy and discrimination risks, or at least fail to limit such risks, be seen as necessary to include in informed consent language? The answer to this question may depend upon what the potential consequences of including this information in the consent document might be. A starting query of interest is whether and how information disclosed in an informed consent document could affect individuals’ perceptions of risk and, subsequently, their willingness to consent and move forward with participation in the research project.

35. Laura M. Beskow et al., *Informed Consent for Biobanking: Consensus-Based Guidelines for Adequate Comprehension*, 17 GENETICS MED. 226, 226 (2015) (conducting a Delphi study to determine consensus for what constitutes adequate comprehension for valid informed consent in biobanking).

36. *Id.* at 230.

37. *Id.*

This Section summarizes key findings from a recent empirical study that sought to assess whether and how informed consent language affects individuals' willingness to participate in a hypothetical genomic study and concerns of genetic discrimination. The study, the results of which are published in full in other work,³⁸ surveyed 1195 individuals using Qualtrics Research Services in June and July 2020. The survey was open to US adult residents and quotas were set for age, gender, race/ethnicity, educational attainment, and household income in order to approximate the US general population.³⁹

C. Experimental Design

Near the beginning of the survey, participants received a brief description of a hypothetical genomic study and sample informed consent language. The primary experimental design of the study was to randomize participants based on two manipulations.

First, participants were randomized into two groups and were presented language inviting them to join a hypothetical research study. One group was invited to a research study about Alzheimer's disease and the other group was invited to a research study about diabetes (Table 1). The rationale for including different types of diseases as part of the experimental design was to assess whether any differences in participant beliefs about willingness to participate in the study or their concerns about genetic discrimination were related to whether the hypothetical study was about a treatable (diabetes) or untreatable (Alzheimer's) disease.⁴⁰ In the disease scenario descriptions we specifically noted that for Alzheimer's disease "there are currently no prevention methods or treatments available for this

38. Anya E.R. Prince et al., *The Goldilocks Conundrum: Disclosing Discrimination Risks in Informed Consent*, 00 J. GENETIC COUNSELING 1, 1 (2022).

39. *Id.* at 1–10.

40. *See, e.g.*, Charles N. Rotimi & Patricia A. Marshall, *Tailoring the Process of Informed Consent in Genetic and Genomic Research*, 2 GENOME MED. 1, 4 (2010) (noting that the disease under investigation in a study could affect individuals' willingness to participate in genetic studies in part due to concerns of stigmatization); in actuality, the underlying study found no statistically significant findings related to disease scenarios. Prince et al., *supra* note 38, at 11.

condition.” In contrast, we described diabetes as “a condition that can be prevented and treated with medication and behavioral changes.” (Table 1).

Table 1: Scenarios Presented

Scenario 1	Imagine you have been asked to participate in a research study about genetic causes of disease. As part of the study, you are asked to take a genetic test to assess your risk of <u>Alzheimer’s disease, a serious condition that causes a decline in mental function. There are currently no prevention methods or treatments available for this condition.</u> The researchers are planning to return the test results to you, so these test results may end up in your medical record.
Scenario 2	Imagine you have been asked to participate in a research study about genetic causes of disease. As part of the study, you are asked to take a genetic test to assess your risk of <u>diabetes, a condition that can be prevented and treated with medication and behavioral changes.</u> The researchers are planning to return the test results to you, so these test results may end up in your medical record.

Second, participants were randomized to receive one of three informed consent languages, with each—Basic Disclosure, Minimum Disclosure, and Comprehensive Disclosure—varying in the level of information provided about legal protections for genetic discrimination (Table 2). The language of the Basic Disclosure is pulled directly from the OHRP guidance on GINA and informed consent. It includes information about GINA’s protections, but explicitly notes that the law does not cover life, disability, or long-term care insurers. In the Minimum Disclosure, participants were presented with the information about GINA’s protections, but the call-out of the gap for life, disability, and long-term care insurance was removed. Finally, in the Comprehensive Disclosure, participants received all the language from the Basic Disclosure, but further gaps in GINA were explicitly highlighted, such as lack of protection for the military,

lending and mortgage companies, educational institutions, and other insurances.

This experimental manipulation was included to assess whether the amount of information about legal protections included in an informed consent document affects participants' perceptions about willingness to participate in the study and their concerns of genetic discrimination. The hypothesis was that those who were provided more information about the risk of genetic discrimination would be less likely to want to participate in the hypothetical study and would be more concerned about genetic discrimination.

Table 2: Informed Consent Presented

Informed Consent Presented	
Basic Disclosure	<p>A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:</p> <ol style="list-style-type: none"> 1. Health insurance companies and group health plans may not request your genetic information from genetic tests. 2. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. 3. Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment. <p>This law does not protect you against genetic discrimination by companies that sell life insurance, disability income insurance, or long-term care insurance.</p>
Minimum Disclosure	<p><i>Full language of consent 1, with the following language removed:</i></p>

	This law does not protect you against genetic discrimination by companies that sell life insurance, disability income insurance, or long term care insurance.
Comprehensive Disclosure	<p style="text-align: center;"><i>Full language of consent 1, with the following language <u>added</u>:</i></p> <p>Additionally, GINA does not regulate other companies, such as educational institutions, military branches, lending and mortgage companies, or other insurances, such as auto, homeowners, or travel insurance.</p>

After receiving the randomly-assigned information about the hypothetical study and one of the three consent languages, participants were asked three questions to assess primary outcome measures.

1) Willingness to participate: *After reading these statements describing your protections against genetic discrimination, how likely are you to participate in the study?* (Measured on a 7-point Likert scale)⁴¹

2) Perceived risk of genetic discrimination: *Based on the informed consent language, do you believe you are at risk of genetic discrimination?* (Measured on a 7-point Likert scale)⁴²

3) Ease of deciding: *How easy was it to decide whether or not you wanted to participate in the study?* (Measured on a 7-point Likert scale)⁴³

D. Findings

The primary findings of this survey showed that individuals who received the Minimum Disclosure were more willing to participate in the hypothetical study than those who received either the Basic or Comprehensive Disclosures and had lower perceived risk of genetic discrimination than those who received the Comprehensive Disclosure (Figure 1). Therefore, those

41. 1 corresponded to ‘not at all likely’ and 7 corresponded to ‘very likely.’

42. 1 corresponded to ‘not at all at risk’ and 7 corresponded to ‘at high risk.’

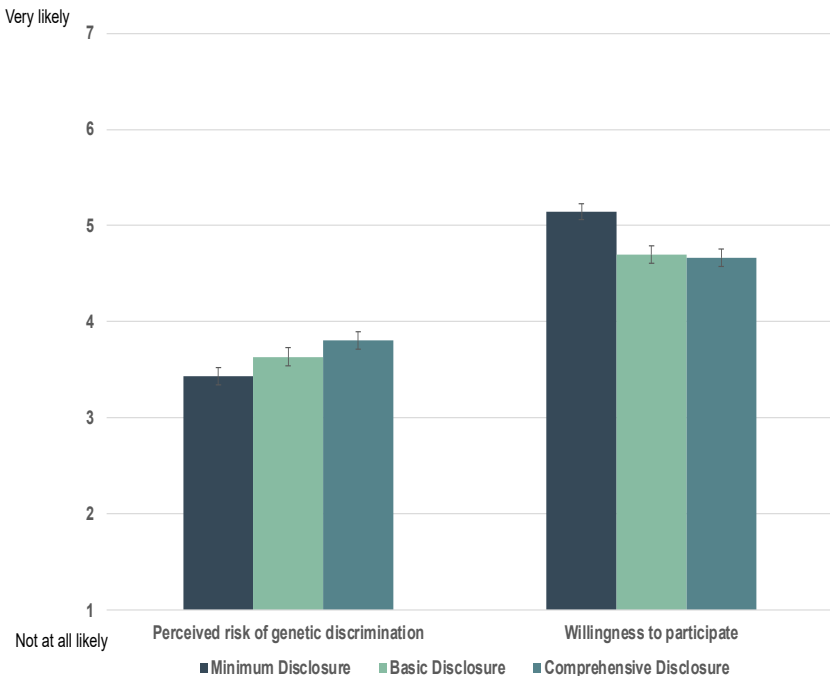
43. 1 corresponded to ‘very difficult’ and 7 corresponded to ‘very easy.’

participants who received no information about the gaps in GINA were more willing to participate in the hypothetical study. The results related to willingness to participate held in regression analyses that factored in participant demographics and other knowledge.⁴⁴

1. Willingness to Participate

Participants reported an overall willingness to participate in the hypothetical study (Mean=4.84, SD=1.77).⁴⁵ However, the average willingness to participate for those receiving the Minimum Disclosure was statistically significantly higher than the other two groups ($F(2, 1192)=9.26, p<.001$) (Figure 1). There was no statistical difference between willingness to participate across the disease scenarios.

Figure 1



44. Prince et al., *supra* note 38, at 4.

45. *Id.* at 5.

2. Perceived Risk of Discrimination

Participants generally reported that they had a low perceived risk of genetic discrimination ($M=3.62$, $SD=1.85$).⁴⁶ However, those who received the Minimum Disclosure consent were statistically significantly less likely to believe that they were at risk than those who received the Comprehensive Disclosure ($F(2, 1192)=3.99$, $p=.02$) (Figure 1). As with the willingness to participate, there was no significant difference between perceived risk of discrimination and the disease scenarios.

3. Ease of Decision

Overall, participants found it relatively easy to make the decision to join the hypothetical study ($M=5.51$, $SD=1.38$).⁴⁷ In this case, there was no statistically significant differences between either the disease scenarios or the consent presented.

In conclusion, the three key outcome measures (willingness to participate, perceived risk of discrimination, and ease of decision to join the study) did not vary statistically between those participants who were asked to join a study about Alzheimer's disease versus those asked to join a study about diabetes. However, there was a statistically significant difference in willingness to participate between participants shown different consent language. Those participants who were shown the Comprehensive Disclosure were less willing to participate and, when compared with those viewing the minimum disclosure, more concerned about genetic discrimination. Thus, receiving more information about the limitations of GINA's scope seemed to impact how participants thought about the risks and benefits of joining the hypothetical study.

The empirical research presented in this paper explores whether the extent of disclosures about genetic discrimination risks can affect individuals' willingness to participate in a hypothetical research study. The findings clearly have important implications for informed consent in the genomic research context. They could potentially have implications for the treatment context and for privacy and discrimination risks

46. *Id.*

47. *Id.*

beyond genetic discrimination. The following two sections explore these potential implications.⁴⁸

IV. POTENTIAL IMPLICATIONS FOR CLINICAL CARE

It is easiest to argue that the empirical findings presented above have relevance for the informed consent process for clinical genetic testing or sequencing.⁴⁹ If individuals' willingness to participate in a hypothetical research study varies based on the extent of disclosure of legal protections, it is foreseeable that similar disclosures during consent for genetic testing in clinical care could have an impact on willingness to pursue testing. This hypothesis is bolstered by real-world data that has found that individuals have failed to get medically recommended clinical genetic testing for fear of genetic discrimination.⁵⁰

However, it is more difficult to definitively say whether these findings would translate into similar individual reactions regarding learning more about broader privacy and discrimination risks in clinical informed consent. The consideration of non-medical privacy and discrimination disclosures in informed consent are unique and complex in the clinical context. For starters, although both research and clinical care rest on the importance of informed consent, the development of the principle has been different in each sector. Additionally, there are some key differences between research and clinical care that have practical implications for informed consent disclosures in the clinical setting. As this section will make clear, given the historical background and key differences between research and clinical care, further interrogation beyond the scope of this paper is needed to fully understand the potential implications of disclosure of legal protections related to privacy and discrimination risks in

48. For the discussion of whether the empirical findings have implications for clinical informed consent, *see infra* Section IV. For the discussion of whether the empirical findings have implications for privacy and discrimination risks beyond genetic discrimination, *see infra* Section V.

49. *See supra* text accompanying note 32.

50. *See, e.g.*, Mark A. Rothstein, *Time to End the Use of Genetic Test Results in Life Insurance Underwriting*, 46 J. L. MED. & ETHICS 794 (2018).

informed consent in the clinical setting and to make recommendations in this regard.

*A. Development of Informed Consent in Research and Clinical
Care*

Although informed consent in both research and clinical care is important to meet foundational ethical principles of autonomy and respect for individuals, the legal mechanisms by which the doctrines were developed, and the underlying motivations for these developments, are different in each setting. Additionally, the standards applied to informed consent rules have meaningful distinctions.

1. Informed Consent Requirements

In the clinical setting, informed consent doctrine was established principally through case law and was historically “more focused on financial compensation for unfortunate medical outcomes than on either the disclosure of information or the consent of the patient in general.”⁵¹ Clinical informed consent doctrine was first established in cases brought under tort theories of battery.⁵² For example, in an early famous case, *Mohr v. Williams*, a patient sued for battery when, after she had consented to surgery on her *right* ear, the physician had operated on her *left* ear.⁵³ The court held that the physician was liable for battery since he had not received express consent to operate on the ear he operated on.⁵⁴

Thus, the *Mohr* case linked consent to battery claims. It was not until over fifty years later that courts began to shift towards recognizing a duty to disclose information as a necessary component of consent in medical malpractice cases, including negligence cases.⁵⁵ Throughout this history, the cases arose in

51. FADEN & BEAUCHAMP, *supra* note 1, at 3.

52. *Id.* at 26.

53. *Mohr v. Williams*, 104 N.W. 12 (1905); for a detailed discussion of this and other twentieth century battery cases related to consent, see FADEN & BEAUCHAMP, *supra* note 1, at 119–25.

54. *Id.* at 121.

55. *Salgo v. Leland Stanford Jr. University Board of Trustees*, 154 Cal. App. 2d 560, 578 (1957); FADEN & BEAUCHAMP, *supra* note 1, at 119–25; *Natanson v. Kline*, 350 P.2d 1093, 1095 (1960).

malpractice claims, making the focus on liability of physicians, rather than on moral principles underlying the importance of consent.⁵⁶

In the research setting, informed consent doctrine developed through ethical guidance that was eventually codified into regulation. The first major ethical guidance regarding human subjects research was the Nuremberg Code—a guidance document created after the trials of Nazi physicians.⁵⁷ Following the atrocities of research on human subjects undertaken during World War II, the Nuremberg Code set out ten principles necessary for ethical research.⁵⁸ The first principle is that “the voluntary consent of the human subject is absolutely essential.”⁵⁹

In the decades following the Nuremberg Code, biomedical and behavioral experimentation increased and several infamous unethical research projects came to light in the US, including the well-known Tuskegee Syphilis Trial.⁶⁰ These developments eventually led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.⁶¹ This committee produced the Belmont Report—a document that outlines the basic ethical principles undergirding biomedical and behavioral human subjects research.⁶² In this work, respect for persons is seen as the foundational ethical principle underlying informed consent, with respect for persons conceptualized as closely linked with respecting individual

56. See, e.g., Valerie Gutmann Koch, *Eliminating Liability for Lack of Informed Consent to Medical Treatment*, 53 U. RICH. L. REV. 1211, 1219–23 (2018) (presenting the critiques of informed consent in the clinical space as being overly focused on defense against liability).

57. 2 Trials of War Criminals Before The Nuremberg Military Tribunals Under Control Council Law No. 10 181–82 (1946-1949) [hereinafter *The Nuremberg Code*]; FADEN & BEAUCHAMP, *supra* note 1, at 153–54.

58. *The Nuremberg Code*, *supra* note 57.

59. *Id.*

60. FADEN & BEAUCHAMP, *supra* note 1, at 151–99.

61. OFF. OF THE SECRETARY: THE NAT'L COMM'N FOR THE PROT. OF HUM. SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RSCH., BELMONT REPORT (1979) [hereinafter *The Belmont Report*].

62. *Id.*

autonomy.⁶³ Thus, the informed consent process is understood as an essential aspect of facilitating individual autonomy and choice in deciding whether to join in a research project.

The Belmont Report was subsequently developed into federal regulation regarding human subjects research, called the Common Rule.⁶⁴ The Common Rule sets out rules for federally sponsored research across multiple agencies and departments.⁶⁵ A key component of the regulations is the codification of rules for informed consent.⁶⁶

2. Informed Consent Standards

Overall, there are three potential legal standards that define the bounds of what must be disclosed during informed consent: 1) the reasonable provider standard; 2) the reasonable person standard; and 3) the subjective standard.⁶⁷ Under the first standard, also called the professional practice standard, informed consent documents should include information that is dictated by professional standards or the customary norms of providers or researchers in the field.⁶⁸ The second standard follows an objective standard and requires informed consent to include the information that a reasonable person would want to know when

63. *Id.* The Belmont Report also highlights a second major aspect of respect for persons, which is to protect those with diminished autonomy. Thus, the Belmont Report, and subsequent regulations, establish rules to protect those who are unable to consent to research. This element of respect for persons is beyond the bounds of this discussion; *see also* Sawicki, *supra* note 5, at 827–28 (discussing the ethical principle of decisional autonomy as a foundation of clinical informed consent).

64. HEALTH & HUM. SERVICES OFF. OF HUM. RSCH. PROT., FED. POL'Y FOR THE PROT. OF HUM. SUBJECTS ('COMMON RULE') (2016).

65. Originally, the Common Rule was developed for 15 agencies and departments. Four additional departments and agencies followed the Common Rule through statute or executive order. After the revisions of the Common Rule in 2018, twenty agencies and departments now follow these rules. *Id.*

66. 45 C.F.R. pt. 46 (2017); Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017).

67. *See* Robert F. Weir & Jay R. Horton, *DNA Banking and Informed Consent: Part 1*, 17 IRB: ETHICS & HUM. RSCH. 1, 3 (1995).

68. *Id.*; FADEN & BEAUCHAMP, *supra* note 1, at 30.

deciding to participate in the research study or to undertake the clinical procedure.⁶⁹ Some have also framed this disclosure requirement, not just as what the reasonable person would want to know, but also what they would expect to be told.⁷⁰ Finally, the third standard commands informed consent to be tailored to the information that an individual person would subjectively desire to know prior to making the decision to continue with the research or treatment.⁷¹

Arguably, this subjective standard best meets the ethical principle underlying informed consent, respect for persons.⁷² “The consent process embodies our recognition that, because different people have different conceptions of what a good life consists of, they will want different sorts of information.”⁷³ Thus, in order for an informed consent document to meet lofty ethical goals of respect for persons and autonomous decision making, truly personalized disclosures should be made.

However, such individualized assessment of potential participants’ and patients’ idiosyncratic and subjective beliefs is cumbersome, if not impossible, in practice.⁷⁴ Legal standards,

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69. Weir & Horton, *supra* note 67, at 3; FADEN & BEAUCHAMP, *supra* note 1, at 32 (noting that “the legal litmus test under this standard for determining the extent of disclosure is the ‘materiality’ or significance, of information to the decision making process of the patient”).
70. See, e.g., Joseph Millum & Danielle Bromwich, *Informed Consent: What Must be Disclosed and What Must be Understood?*, 21 AM. J. BIOETHICS 46, 55 (2021).
71. Weir & Horton, *supra* note 67, at 3.
72. FADEN & BEAUCHAMP, *supra* note 1, at 34.
73. Erik Parens, *Drifting Away from Informed Consent in the Era of Personalized Medicine*, 45 HASTINGS CTR. REP. 16 (2015).
74. Robert F. Weir & Jay R. Horton, *DNA Banking and Informed Consent: Part 2*, 17 IRB: ETHICS & HUM. RSCH. 1 (1995); FADEN & BEAUCHAMP, *supra* note 1, at 34; see also *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (noting that the subjective standard would “summon the physician to second-guess the patient, whose ideas on materiality could hardly be known to the physician”); Sawicki, *supra* note 5, at 859 (noting other practical realities of the subjective standard, such as the potential for hindsight bias and judicial economy); Sheldon F. Kurtz, *The Law of Informed Consent: From Doctor is Right to Patient Has Rights*, 50 SYRACUSE L. REV. 1243 (2000).

therefore, follow objective standards—either the reasonable provider or the reasonable person standard. Additionally, some states have specific informed consent statutes that delineate what information must be included in informed consent documents, both clinical and research.

In the clinical setting, approximately half of states follow the reasonable provider standard, which requires the provider to disclose what others in their field would usually disclose.⁷⁵ Most other states have adopted the reasonable patient standard, made famous by *Canterbury v. Spence*.⁷⁶ In *Canterbury*, the court described the standard as, “when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.”⁷⁷ Common law cases regarding informed consent generally have required disclosure of information about the proposed treatment, the risks and benefits of the treatment, alternative procedures, and the risks or benefits of taking no action.⁷⁸ These categories are generally the same under both the reasonable provider and reasonable patient standards, as well as state statutes that delineate consent requirements.⁷⁹

In the research setting, the Common Rule adopted a reasonable person standard. “The prospective subject . . . 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 . . .”⁸⁰ Thus, there is no equivalent reasonable researcher standard within the research setting akin to the reasonable provider standard.

75. Michael Flynn, *Informed Consent: Does “OK” Really Mean “OK?”*, 16 J. HEALTH & BIOMEDICAL L. 29, 34 (2019); I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, 108 GEO. L. J. 1425 (2019).

76. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); Cohen, *supra* note 75.

77. *Canterbury*, 464 F.2d at 787.

78. Sawicki, *supra* note 5, at 831.

79. *Id.*

80. 45 C.F.R. § 46.116(a)(4) (2018).

B. Key Differences between Research and Clinical Care

Other key differences between clinical care and research create differing considerations pertinent to informed consent and how disclosure of broader privacy or discrimination risks may impact patients' decisions. This section will briefly introduce the differences, although future work should further analyze the full impact of these considerations on recommendations for expanding the scope of non-medical risk disclosures in clinical informed consent.

First, the reasons for undergoing a procedure in clinical care are often different than in the research setting. In research, the goal of the investigation is to build generalizable knowledge—that is, the goal of research is not specifically to provide a benefit to any particular participant.⁸¹ In contrast, clinical care naturally seeks to treat an individual patient. This distinction is important for informed consent because it alters the calculus of weighing risks and benefits. In research there may be no direct benefit to the participant and therefore understanding the full scope of possible risks is important when deciding whether to participate.⁸² In contrast, when consenting to treatment that is specifically for their own benefit, patients may find non-medical risks to be less relevant since the medical implications of not undertaking the procedure may be of greater detriment than accepting the various risks associated with the procedure.

Interestingly, the calculus for weighing risks and benefits of clinical genetic testing may, in some instances, be more akin to balancing in the research realm. This is because some clinical genetic testing is completed preventatively in asymptomatic individuals in order to help them understand future risk. This may be why the empirical findings could translate more directly to clinical genetic testing and why there is empirical evidence of

81. See 45 C.F.R. § 46.102(1) (2017) (defining research to be “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”).

82. See, e.g., Jeffrey R. Botkin, *The Bane of “Boilerplate” Language in Research Consent Forms: Ensuring Consent Forms Promote Autonomous Authorization*, 19 AM. J. BIOETHICS 83, 83 (2019) (noting that participating in research studies is ‘supererogatory’ and thus the consent forms for research are more extensive than in the clinical setting).

individuals opting to decline clinically recommended genetic testing because of privacy concerns.⁸³

Second, the ease of disclosing risks is different across both clinical care and research. In research, the relationship between a researcher and participant generally begins with the informed consent process, which includes a conversation with a study team member and signing of a written informed consent document.⁸⁴ In contrast, informed consent in clinical care does not always occur at the beginning of the relationship between a physician and a patient. Additionally, consent in the clinical setting is not always written, so in-depth disclosure of nuanced non-medical risk information may be more complicated for a number of different procedures, and this may impact how patients absorb and synthesize risk information.

Third, there are other mechanisms within the clinical setting where pertinent information about privacy and discrimination risks can be disclosed. Most notably, patients receive notice about health information privacy protections through requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.⁸⁵ It may be that these disclosures sufficiently provide the opportunity for patients to learn about non-medical privacy risks associated with clinical care.⁸⁶

83. *See, e.g.*, Rothstein, *supra* note 50.

84. Some research projects challenge this general mold. For example, written informed consent can be waived in the case of research in the emergency setting. Additionally, as will be discussed further below, some research sits at the intersection of clinical care and research, making informed consent a more complex interaction. *See infra* Section V.A.

85. 45 C.F.R. §§ 164.520(a) and (b) (2013).

86. There are, of course, plenty of critiques that patients do not read HIPAA notices and are not actually aware of the nuances of HIPAA's privacy protections. *See, e.g.*, M.C. Pollio, *The Inadequacy of HIPAA's Privacy Rule: The Plain Language Notice of Privacy Practices and Patient Understanding*, 60 N.Y. UNIV. ANN. SURVEY OF AM. L. 579 (2004). These critiques, however, are not unique to HIPAA notices—informed consent documents themselves are notoriously under-read and misunderstood. Even in the empirical research conducted regarding informed consent and GINA described above in Section III, when survey respondents were asked about the details of GINA, they exhibited poor objective

Finally, there is the practical, on-the-ground reality that disclosure of non-medical risk is a more accepted practice in the research setting.⁸⁷ For example, of the nine delineated elements of basic informed consent in the Common Rule, two explicitly relate to non-medical risks—researchers must disclose: 1) the extent of confidentiality practices, and 2) when relevant, a description that data from the research project may be de-identified and shared in the future.⁸⁸ In contrast, there have been calls to expand clinical informed consent to include information about non-medical risk information, but these have been predominantly aspirational to date.⁸⁹ These recommendations have not been widely incorporated into common law doctrine or state statutes that delineate informed consent requirements.

knowledge of the law, even though they had just read a summary of the law's protections. Prince et al., *supra* note 38.

87. *See, e.g.*, OHRP Guidance, *supra* note 6. The acceptance of expansion of consent to non-medical risks and aspects of has generally come from statutory requirements, like the Common Rule. At common law, courts have not always been sympathetic to claims regarding researchers' duties to inform participants of non-medical aspects of the project. *See, e.g.*, Greenberg v. Miami Children's Hospital Research Institute, Inc., 264 F.Supp.2d 1064, 1070-1071 (S.D. Florida 2003) (holding that researchers do not owe a duty to disclose potential economic interests to participants in informed consent documents). This requirement, however, has since been statutorily added for economic interests related to biospecimens to the revised Common Rule as an additional element of informed consent. 45 C.F.R. § 164.116(c)(7) (2018) (noting that informed consent documents must include, when appropriate, "a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit").
88. 45 C.F.R. §§ 46.116(b)(5) & (9) (2018).
89. *See generally* Sawicki, *supra* note 5 (arguing that non-medical information should be disclosed to patients during informed consent when it is within the physician's knowledge and expertise and would be material to a reasonable patient); *see also* Wiltbank, *supra* note 17 (discussing trends in case law requiring disclosure of physician inexperience with a particular procedure during informed consent); Hanson, *supra* note 17 (exploring when a physician may need to disclose information about personal factors, such as drug or alcohol use or medical condition, or about financial interests); *but see* Kurtz, *supra* note 74 (highlighting a case where a court found that surgeon experience should be disclosed to patients).

This differing uptake of disclosed information has implications for what legally must be disclosed under informed consent standards. For example, the reasonable provider standard may, by its nature, limit the extent to which non-medical risk information can be rapidly expanded. This is because if the standard is to disclose what the average provider would disclose, it is very difficult to move the needle towards greater disclosures. For example, in the context of disclosing risk of genetic discrimination, it may be sufficient to disclose that GINA does not cover life, long-term care, and disability insurances without going into detail about other entities that GINA fails to protect, since it is likely that this is the greatest level of detail that many providers would disclose. In contrast, under a reasonable person standard, it may arguably be necessary to provide greater detail about risks and legal protections because data, such as the empirical work presented in this paper, can show what types of information are relevant to an individual's decision to undergo a procedure or participate in a study.

Overall, there are many differences between clinical care and research that complicate how to assess the potential implications for clinical care of the fact that disclosure of more information about legal protections affects individuals' willingness to join research studies. While it is possible that the findings of the empirical study presented in this paper may translate into the clinical realm, greater research and empirical study is needed to fully understand whether and how disclosing greater information about privacy and anti-discrimination laws and their limitations would alter patient perceptions about the risks and benefits of undergoing treatment procedures.

V. POTENTIAL IMPLICATIONS FOR RESEARCH

There are many complex reasons why it is difficult to directly draw implications of the empirical work presented in this paper for clinical care; however, there are clearer, but no less thorny implications for research. The empirical work focuses on foreseeable genetic discrimination risks to show how varying the level of disclosure about legal protections may affect individuals' willingness to participate in a research study and their

perceptions of risks for discrimination. Yet, there are many foreseeable privacy and anti-discrimination laws that are likely equally relevant for participants to understand in order to appreciate the breadth of privacy risks associated with joining a research study.

These laws raise similar issues of drawing lines regarding how much information to disclose, both within genomic research studies and within other types of research. It is likely that reasonable participants would want to learn of a variety of relevant legal protections and their limitations, but it is also easy to imagine that highlighting gaps in the legal protections could make people more wary about participating in research or fearful of discrimination.⁹⁰

Modern research is simultaneously increasing the likelihood that participants will be exposed to non-medical privacy risks and, for some types of research, limiting the scope of medical risks. Such privacy risks can lead to a variety of potential harms, from economic to social to psychological.⁹¹ Therefore, this section argues that it is likely that a reasonable participant would desire information about a broad range of foreseeable privacy and discrimination risks associated with the study and that disclosure of both legal protections and limitations of the law may be necessary to facilitate understanding of the risks.

90. Numerous studies have found that concerns about privacy have led individuals to decline participation in research. *See, e.g.*, Ellen W. Clayton et al., *A Systematic Literature Review of Individuals' Perspectives on Privacy and Genetic Information in the United States*, 13 PLOS ONE 1, 11 (2018).

91. NAT'L RSCH. COUNCIL, PROPOSED REVISIONS TO THE COMMON RULE FOR THE PROT. OF HUM. SUBJECTS IN THE BEHAVIORAL AND SOC. SCI. 113 (Washington, DC: The National Academies Press) (2014) ("The most relevant harms from information disclosure are potential economic harms (e.g., loss of job, insurance coverage, or economic assets), social harms (e.g., loss or damage to social relationships such as marriage), or criminal or civil liability (e.g., arrest for illegal behavior)). Also, information made known in some contexts can increase the risk of physical harm (e.g., spouse abuse) or psychological harm (e.g., personal information if revealed could trigger depression)") [hereinafter NRC Proposed Revisions].

A. Technological Advances Increase Non-Medical Risks

Advances in research are increasing the complexity and scope of potential privacy and discrimination risks to prospective participants.⁹² Three advances particularly expand the potential scope of risks and add challenges for informed consent. First, due to technological advances, the scope of information collected about an individual is greatly expanded. Research studies increasingly utilize large-scale personal data and biospecimens.⁹³ For example, genomic research studies combine personal and behavioral data or other biomarkers with genetic information, creating robust datasets about individuals.⁹⁴ In some research contexts, individuals are asked to use technology, such as a smart phone app or electronic medical device, that collect copious

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92. For example, the Preamble to the revised Common Rule, published in 2017, describes the wide-ranging changes in human subjects research that had occurred in the past two decades: “Since the Common Rule was promulgated, the volume and landscape of research involving human subjects have changed considerably. Research with human subjects has grown in scale and become more diverse. Examples of developments include: an expansion in the number and types of clinical trials, as well as observational studies and cohort studies; a diversification of the types of social and behavioral research being used in human subjects research; increased use of sophisticated analytic techniques to study human biospecimens; and the growing use of electronic health data and other digital records to enable very large datasets to be rapidly analyzed and combined in novel ways.” Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017) (codified at 45 C.F.R. pt. 46 and other scattered sections).
93. See, e.g., Leighton Chan, Patrick McGarey, Joseph A. Sclafani, *Using Large Data Sets for Population Based Health Research*, in PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH 293 (John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson eds., 4th ed. 2018) (discussing the use of large data-sets in health research); see also Vivian Tam et al., *Benefits and Limitations of Genome-Wide Association Studies*, 20 NATURE REVIEWS GENETICS 467 (2019) (discussing genomic research that aggregates the data of many individuals to identify genetic associations).
94. Grady, *Enduring and Emerging Challenges of Informed Consent*, *supra* note 2, at 859. The genetic sequencing data on its own already raises numerous informed consent issues with greater amounts of recommended disclosures.

amounts of information.⁹⁵ Greater amounts of personal data in the hands of research teams lead to greater risks of loss of privacy and discrimination.⁹⁶ Additionally, with the burgeoning collection of individual data, researchers are incorporating artificial intelligence and machine learning into studies. Such use of these cutting edge technologies raises unique privacy and discrimination concerns.⁹⁷

Second, modern research often leads to broad data sharing for future research—in part to leverage individual information into big data and artificial intelligence.⁹⁸ For example, pooling genetic information into large biobanks is common to enable secondary research.⁹⁹ This data is often shared without the consent of the individual because the data is deidentified.¹⁰⁰

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95. See generally Stacey A. Tovino, *Going Rogue: Mobile Research Applications and the Right to Privacy*, 95 NOTRE DAME L. REV. 155 (2019) (discussing the potential privacy risks of using health apps in research).
96. NRC Proposed Revisions, *supra* note 91, at 109.
97. A.M. Froomkin, *Big Data: Destroyer of Informed Consent*, 21 YALE J.L. & TECH. 27, 30 (2019); Anya E.R. Prince & Daniel Schwarcz, *Proxy Discrimination in the Age of Artificial Intelligence and Big Data*, 105 IOWA L. REV. 1257 (2019).
98. The benefits and risks of this broad data sharing have been debated elsewhere and will not be re-litigated here. See, e.g., Clayton et al., *supra* note 90, at 14 (highlighting how genomic data sharing is a critical goal endorsed by many to improve research); but see Parens, *supra* note 73, at 16 (arguing that our excitement about technological advances is drawing society away from basic tenets of informed consent).
99. Kathleen Liddell & Jeffrey M. Skopek, *Informed Consent for Research Using Biospecimens, Genetic Information and Other Personal Data*, Univ. Cambridge Fac. L. Rsch. Paper (2017).
100. Once patient or participant information is deidentified, both the Common Rule and HIPAA allow for large-scale sharing of data without consent. The Common Rule defines human subjects research to include direct intervention or interaction with an individual or secondary research using identifiable private information or identifiable biospecimens. 45 C.F.R. § 46.102(e) (2018). Thus, de-identified information or biospecimens are not considered human subjects research and do not have to comply with the informed consent regulations of the Common Rule. Similarly, the HIPAA Privacy Rule defines protects health information as “individually identifiable health information . . .”

Additionally, even identifiable information can be used for future secondary research without specific consent if there has been either broad consent received by the individual initially¹⁰¹ or a waiver of informed consent requirements by an IRB.¹⁰²

Growing use of large scale existing datasets and genomic data narrow the amount of medical information collected directly from participants, which naturally diminishes medical risks associated with participation in the study. However, sharing of data across researchers, institutions, and even international borders for secondary research increases threats to privacy and confidentiality of the data.¹⁰³ Indeed, when research is conducted on secondary data, none of the traditional, physical risks of clinical research or care are present—the risk becomes entirely non-medical and related to data privacy and protection.¹⁰⁴

and envisions allowable sharing of deidentified data. 45 C.F.R. § 160.103 (2013).

101. 45 C.F.R. § 46.116(d) (2018). Broad consent is a consent mechanism that was added to the revised Common Rule. It requires participants to be informed of details regarding how their identifiable data may be shared in the future, such the types of institutions with which their data may be shared. Once broad consent is received from the individual, their identifiable data can be used for secondary research in the future. Barbara E. Bierer, et al., *Revised ‘Common Rule’ Shapes Protections for Research Participants*, 36 HEALTH AFF. 784, 786 (2017) (arguing, however, that this option is less likely to be used than other options such as deidentifying data or obtaining a waiver); see also David M. Parker et al., *Privacy and Informed Consent for Research in the Age of Big Data*, 123 PENN ST. L. REV. 703, 727 (2018) (similarly arguing that broad use of broad consent is unlikely).
102. 45 C.F.R. § 46.116(f) (2018). The IRB can only waive the informed consent requirements if: the research involves no more than minimal risk, it could not be practicably carried out without using such information or biospecimens in an identifiable format, and the waiver would not adversely affect the rights and welfare of the subjects. 45 C.F.R. § 46.116(f)(3) (2018).
103. See, e.g., Gail E. Henderson, *Is Informed Consent Broken?*, 342 AM. J. MED. SCI.’S 267, 271 (2011) (highlighting how broad data sharing raises concerns of privacy and confidentiality threats and describing the challenges raised by large-scale genomic research as a “paradigm shift in our approach to human subject protection”).
104. See, e.g., Juli Murphy et al., *Public Perspectives on Informed Consent for Biobanking*, 99 AM. J. PUB. HEALTH 2128 (2009) (discussing the unique concerns regarding informed consent in bio

Thus, with data sharing, traditional informed consent is turned on its head because an individual's data may be used in research by scientists removed from the original research study or clinical care that collected the information.¹⁰⁵ Secondary use of the copious amount of patient and participate data for further research increasingly requires individuals to be informed of complex privacy and data security measures, as well as information about de-identification of data.¹⁰⁶

Finally, the dividing line between research and clinical care is becoming increasingly blurry.¹⁰⁷ Translational research studies

banking); Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7151 (Jan. 19, 2017); *see also* NRC Proposed Revisions, *supra* note 91, at 109 (noting that this is true for most primary social and behavioral research, not just secondary research).

105. *See* Jodyn Platt et al., *Public Preferences Regarding Informed Consent Models for Participation in Population-based Genomic Research*, 16 GENETICS IN MED. 11 (2014) (“Trends in scientific research toward the use of large-scale biobanks and long-term population-based longitudinal studies challenge the traditional role of informed consent as a social contract between a single research team and an individual participant”).

106. The data used in secondary research is often de-identified. Under HIPAA and the Common Rule, specific informed consent is not required from individuals to use their de-identified information for this research. However, when prospectively enrolling participants into research where there are plans to continue to use samples for secondary research, it is customary to detail this in the informed consent document. *See, e.g.*, Clayton et al., *supra* note 90 (indicating that HIPAA and the Common Rule allow for research on de-identified data without consent, but, in the context of genomic data sharing, NIH requires researchers to obtain consent from participants for sharing data to databases that enable such research); additionally, as will be discussed further below, the greater sharing of individual data across researchers makes it much more difficult to clearly or precisely define what the full scope of non-medical risks to an individual may be. Platt et al., *supra* note 105, at 11.

107. This is not to suggest that the line between clinical care and research has always been historically distinct. *See generally* Tom L. Beauchamp & Yashar Saghai, *The Historical Foundations of the Research-Practice Distinction in Bioethics*, 33 THEORETICAL MED. & BIOETHICS 45 (2012) (delineating the historical reasons why there has been a distinction made between research and clinical practice

sit at the intersection between research and clinical care and aim to identify novel findings, but also discover the best methods to implement the findings into clinical care. Genomics research projects seek to translate basic science findings into actionable clinical care.¹⁰⁸ Learning health systems aim to improve patient care by collecting data and metrics about patient care and convert this into system wide reforms of practice.¹⁰⁹ These systems that straddle research and clinical care implicate two different set of legal rules and ethical frameworks, increasing the complexity of relevant privacy and discrimination risk information.¹¹⁰

These three advances—the rise of big data, the use of secondary data, and the blurred boundaries between research and clinical care—are all related and intertwined. Overall, they have led to a situation where much of human subjects research is no longer focused on the individual themselves, but on their data, whether originating from clinical care or research.¹¹¹ Such focus

and noting that this dividing line has always been fuzzy and nuanced).

108. Susan M. Wolf et al., *Integrating Rules for Genomic Research, Clinical Care, Public Health Screening and DTC Testing: Creating Translational Law for Translational Genomics*, 48 J. L. MED. & ETHICS 69 (2020).
109. See, e.g., Harlan M. Krumholz, *Big Data and New Knowledge in Medicine: The Thinking, Training, and Tools Needed for a Learning Health System*, 33 HEALTH AFF. 1163 (2014).
110. See, e.g., Wolf et al., *supra* note 108 (delineating the complexities of legal frameworks, professional norms, and ethics across translational genomics); see also Grady, *Enduring and Emerging Challenges of Informed Consent*, *supra* note 2 (noting how new models at the intersection of research and clinical care present challenges in determining what information should be presented in informed consent); see also Ruth R. Faden, et al., *Informed Consent, Comparative Effectiveness, and Learning Health Care*, 370 NEW ENG. J. MED. 766 (2014) (highlighting the complexities of collecting informed consent in the context of learning healthcare systems and arguing that, in some instances, specific informed consent of patients is not necessary when there is a broader ethical framework applied to the research and institution overall).
111. Liddell & Skopek, *supra* note 99.

on aggregating copious amounts of data increases the non-medical risks to an individual, while simultaneously making these risks harder to identify and precisely quantify. This presents challenges for researchers to disclose these potential privacy and discrimination risks within the informed consent process.

B. Types of Privacy and Discrimination Risks in Research

Foreseeable loss of privacy and threats of discrimination can result from both unintended and anticipated sharing of data. For example, as discussed above, GINA protects against genetic discrimination in the limited contexts of employment and health insurance. Thus, use of genetic information by life insurers would be legal discrimination at the federal level and, what's more, these life insurers routinely gain permissible access to individuals' medical records and, in some cases research results, as part of standard application procedures. This would be an example of an anticipatable privacy or discrimination risk. On the other hand, an unintended loss of privacy could come from a computer hacker gaining access to research files or an individual re-identifying previously de-identified information.

Informed consent documents generally do disclose the potential of both of these types of non-medical privacy risks, although they vary in how the risks are described and the extent of detail provided, especially regarding the associated legal protections and risks. The Common Rule was revised in 2018, with several key changes made to the rules regarding informed consent.¹¹² One central element of the changes was to make informed consent documents easier to read to facilitate individual understanding.¹¹³ To this end, the revised Common Rule requires consent documents to begin with a concise summary page presenting the information most likely to be relevant to a prospective participant.¹¹⁴ Some of the recommended included information in the revised Common Rule is responsive to the categories of concern delineated below.

112. Jeremy Sugarman, *Examining Provisions Related to Consent in the Revised Common Rule*, 17 AM. J. BIOETHICS 22, 22–26 (2017).

113. *Id.* at 23.

114. 45 C.F.R. § 46.116(a)(5)(i) (2018).

1. Unintended Information Sharing

Data Security

In general, research studies aim to keep participants' research data confidential by limiting wide-spread sharing of identifiable information, storing identifiable data in secure or encrypted locations, and following other data security measures when transferring data. Thus, descriptions of data security measures or controls help participants understand the potential for inadvertent losses of privacy.¹¹⁵ The Common Rule explicitly requires disclosure of the "extent to which confidentiality of records identifying the subject will be maintained."¹¹⁶ This could include information about how data is encrypted, where it is stored, or who has access to the information within an organization. Under the revised Common Rule, the Secretary of HHS is tasked with issuing guidance to assist researchers in assessing privacy risk and establishing adequate data security protocols.¹¹⁷

Reidentification

If an individual's information is deidentified, it can then legally be shared freely among researchers. Most often, this is generally not conceptualized as a threat to the privacy or

115. See, e.g., Weir & Horton, *supra* note 67, at 2 (arguing that consent documents should include information about procedures that will be used to protect confidentiality and privacy of information); see also Barbara A. Bernhardt, et al., *Experiences with Obtaining Informed Consent for Genomic Sequencing*, 167 AM. J. MED. GENETICS 2635, 2642 (2015) (highlighting that individuals consenting have concerns about how their data will be protected and what impacts might be for discrimination).

116. 45 C.F.R. § 46.116(5)(b) (2018).

117. 45 C.F.R. § 46.111(a)(7)(i) (2018); the Advanced Notice of Public Rulemaking (ANPRM) originally floated the idea of adopting the pre-existing HIPAA Security Rule standards for all research studies. This, however, was critiqued in public comments at both the ANPRM and Notice of Proposed Rulemaking (NPRM) stage. The final rule included the plan for future HHS guidance to be established. Federal Register /Vol. 82, No. 12, at 7200–07. Federal Policy for the Protection of Human Subjects. Such guidance has not yet been published.

confidentiality of a participant.¹¹⁸ However, even in the context of sharing de-identified data, there are still some privacy risks given the potential for re-identification.¹¹⁹ Despite this, there does not appear to be extensive discussion in many informed consent documents of the risk that such samples could be re-identified, despite robust discussions that suggest that in the era of big data, true de-identification is virtually impossible to achieve.¹²⁰ Empirical studies of individuals have shown that there are a variety of opinions about concerns of the identifiability of information, but that at least some individuals worry about identifiability and reidentification of their data.¹²¹ This shows that the topic may be pertinent under a reasonable participant standard.

Compelled Disclosures

There are some times when researchers or clinicians could be compelled by law to disclose individual information, such as to public health authorities, to report potential instances of abuse, or when ordered by a court of law.¹²² Thus, some informed consent

118. There have been vigorous debates about whether deidentified information should be conceptualized differently, most notably when the NPRM for the Common Rule suggested requiring consent to share de-identified biospecimens. However, law and policy, from HIPAA to the revised Common Rule, treats deidentified information differently than identified information.

119. *See generally*, Stacey A. Tovino, *Not So Private*, 71 DUKE L. J. 985 (2022) (discussing the increasing literature that shows that previously de-identified data can increasingly be reidentified and analyzing how law and policy can more effectively address reidentification risks); *see also* Parker et al., *supra* note 101, at 727 (arguing that informed consent under the Common Rule will become a ‘sham’ if there is not honest disclosure about reidentification risks).

120. *See* Tovino, *Going Rogue: Mobile Research Applications and the Right to Privacy*, *supra* note 95; Parker et al., *supra* note 101, at 727; Misha Angrist, *Eyes Wide Open: The Personal Genome Project, Citizen Science and Veracity in Informed Consent*, 6 PERSONALIZED MED. 691, 694 (2009).

121. Clayton et al., *supra* note 90.

122. *See, e.g.*, Li Du et al., *Compelled Disclosure of Confidential Information in Patient Safety Research*, 17 J. PATIENT SAFETY 200,

documents may warn individuals of these possibilities, especially when a study is more likely to elicit such information.

Studies funded by the NIH automatically receive a Certificate of Confidentiality if identifiable information is collected. A Certificate of Confidentiality is a federal mechanism that shields researchers from compelled court disclosures of participant information, such as a subpoena.¹²³ As with GINA, the federal government has provided researchers sample model language to include in consent documents, since participants must be told when the study has received a Certificate of Confidentiality.¹²⁴ However, there is legal uncertainty over whether the Certificates of Confidentiality will always protect participant data in the way they are intended, thus complicating disclosure of such protections in informed consent.¹²⁵

2. Anticipatable Information Sharing

For many historical research projects, the majority of privacy risks were from unintended informational breaches. This would be the case if there were no plans to share identifiable research data beyond the research team. However, key aspects of study design and data sharing policies can now increase the risk of revelation of participants' data in ways that can be anticipated.

Study Design

In some instances, the design of a research study may lead to increased risks of loss of privacy. Most notably, some studies are explicitly designed to be 'open' research, where the identifiable results are publicly shared.¹²⁶ In these cases, participants are

202 (2021) (finding, however, that compelled disclosures are rare in practice).

123. Check et al., *supra* note 34.

124. NIH, *Example Informed Consent Language*, NIH: Grants & Funding, <https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm> [<https://perma.cc/4L36-U69W>] (last updated May 23, 2019). Check et al., *supra* note 34, at 1.

125. Check et al., *supra* note 34; Leslie E. Wolf & Laura M. Beskow, *Genomic Databases, Subpoenas, and Certificates of Confidentiality*, 21 GENETICS IN MED. 2681, at 1 (2019).

126. *See generally* Angrist, *supra* note 120; *see also* Wolf et al., *supra* note 108.

clearly told of the potential risks of this information being widely available. However, more subtle study design choices also can greatly affect information sharing and thus privacy and discrimination risks.

One notable study design choice is whether the individual results of research will be placed into the participant's electronic medical record.¹²⁷ In the era of translational research, this is a growing phenomenon. However, placing results in medical records changes the confidentiality of the information, as the rules for when and how data can be shared differs depending on whether an individual's data is part of a research record or clinical record.¹²⁸

Another key study design feature is whether individual results will be returned to participants. Once individuals have access to this information, there may be times when they may be required to share the information in ways that they would prefer not to. For example, if a life insurer asks an applicant a question where a research result could be responsive, the applicant would have to provide the insurer this information or risk potentially committing fraud.¹²⁹ Most individuals, however, likely would not conceptualize getting information themselves as a potential action that increases informational risk in the future, so informed consent documents may need to make this clear.

127. Anya E.R. Prince, et al., *Automatic Placement of Genomic Research Results in Medical Records: Do Researchers Have a Duty? Should Participants Have a Choice?*, 43 J. L. MED. & ETHICS 827 (2015). Even disclosing individualized research results directly to a participant could impact future discrimination risks. For example, one paper argues that participants should be told that insurers could gain access to genetic test results as a required disclosure from the individual within the application process. Gail Geller et al., *Genetic Testing for Susceptibility to Adult-Onset Cancer: The Process and Content of Informed Consent*, 277 J. AM. MED. ASS'N 1467, 1471 (1997).

128. *See, e.g., supra* text accompanying note 115.

129. Anya E.R. Prince, *Tantamount to Fraud: Exploring Non-Disclosure of Genetic Information In Life Insurance Applications As Grounds for Policy Recission*, 26 HEALTH MATRIX 255, 255 (2016).

Data Sharing

As discussed above, growing trends of data sharing, even of de-identified information, greatly increase privacy and discrimination risks. For this reason, informed consent documents often describe when and how researchers plan on sharing participant data, including both identifiable and non-identifiable information.¹³⁰ Sharing of data, especially identifiable data, is seen as extremely important to include in consent documents.¹³¹ For example, a study comparing what information IRB professionals, researchers, and participants felt was most important to disclose found that information about potential release of identifying information was the disclosure endorsed by most groups in the study.¹³² Key, however, to understanding the impact of having one's identifiable information more widely shared is an understanding of how certain actors may be able to use this information to discriminate if they gain access to it. Indeed, concerns about discrimination is often one of the main reasons that individuals are worried about loss of privacy and sharing of information.¹³³

C. Disclosing Legal Protections

The goal of informed consent is to disclose actual foreseeable risks.¹³⁴ Informed consent documents are increasingly including description of the unintended and anticipable informational risks described above, although the breadth and scope of these disclosures vary.¹³⁵ What's more, it is likely that reasonable

130. See, e.g., Weir & Horton, *supra* note 67, at 2 (arguing that consent documents should include information about how researchers will handle third-party access to and secondary use of data and stored DNA samples).

131. Clayton et al., *supra* note 90, at 7.

132. Laura M. Beskow et al., *Simplifying Informed Consent for Biorepositories: Stakeholder Perspectives*, 12 GENETICS IN MED. 567, 569 (2010).

133. Clayton et al., *supra* note 90, at 2.

134. 45 C.F.R. § 46.116(b)(2) (2018); see *supra* Section II.

135. For example, a 1995 survey of 103 consent documents found that 79 of the documents in the DNA biobanking realm had none of the consent documents made sufficient disclosures to satisfy what a reasonable person would want to know about confidentiality

participants would desire information about privacy and discrimination risks.¹³⁶ However, true understanding of the extent of these risks often necessitates a description of current legal protections.¹³⁷ For example, in a genomics study, participants may be warned that they could face genetic discrimination based on results discovered during the research study. However, to truly understand the magnitude and likelihood of such a risk, participants would need to understand the protections, and limitations, of GINA.¹³⁸

In the context of broader concerns of loss of privacy and risk of discrimination, a wide range of laws become relevant, from the federal Americans with Disabilities Act (ADA), the Affordable Care Act (ACA), and HIPAA,¹³⁹ to state specific privacy laws or common law, to more targeted federal laws, such as rules specific to the Armed Forces or federal employees. For some research projects, other specific legal protections may be relevant, such as rules protecting financial data or laws protecting against other

procedures. Weir & Horton, *supra* note 67, at 2; however, later reviews of consent documents show greater inclusion of details about information sharing and potential risks. *See, e.g.*, Jill Oliver Robinson et al., *Participants and Study Decliners' Perspectives about the Risks of Participating in a Clinical Trial of Whole Genome Sequencing*, 11 J. EMPIRICAL RSCH. ON HUM. RSCH. ETHICS 21, at 22-23 (2016) (noting that informed consent documents in a research project included information about, among other risks, insurance discrimination and loss of privacy); moreover, some elements of these disclosures are now explicitly required by the revised Common Rule. 45 C.F.R. §§ 46.116(a)-(b) (2018).

136. For example, one study found that research participants were more likely than IRB professionals and researchers to believe that it was important to disclose privacy risks and information about sharing of identifiable participant data. Beskow et al., *Simplifying Informed Consent for Biorepositories: Stakeholder Perspectives*, *supra* note 132, at 569.

137. *But see* Beskow et al., *Informed Consent for Biobanking: Consensus-Based Guidelines for Adequate Comprehension*, *supra* note 35, at 227-28 (finding that participants did not necessarily believe that understanding of GINA or Certificates of Consent where required for valid consent).

138. OHRP Guidance, *supra* note 6.

139. *See* Clayton et al., *supra* note 90, at 16.

types of discrimination beyond discrimination on the basis of medical traits.

The scope of these legal protections can quickly become staggering. As one systematic review of state laws that regulate genetic testing described:

This project aimed to determine whether and how well state laws fill known gaps in federal laws that protect participants in genomic research. We embarked on this research knowing states had adopted their own laws that sometimes went beyond the floor established by federal laws such as the Common Rule, the HIPAA Privacy Rule, GINA, and the ADA, but we were surprised by the sheer quantity of state laws that we uncovered, even after limiting consideration to laws that expand on federal protection and apply to a large genomic research project . . . The quantity of state laws is striking, standing alone, as it points to the complexity of identifying what protections are afforded to research participants and communicating those protections effectively to participants.”¹⁴⁰

Despite this complexity, it is clear that, just as with GINA, individuals may find that information about legal protections and their limitations are relevant for deciding whether to enroll in the study. For example, if the design of a research study places results in a participant’s medical record, it may become important to disclose several key limitations to privacy protections. First, once research data is placed in a clinical medical record, it is no longer protected by Certificates of Confidentiality.¹⁴¹ Second, once information is placed within an electronic medical record, it is governed by a completely different set of legal rules than research data, notably HIPAA. Researchers may be tempted to simply disclose that information in medical records is protected. However, this focus would ignore the anticipable ways that data within an electronic health record can be shared with outside entities such as employers or insurers, even within the bounds of

140. Leslie E. Wolf et al., *The Web of Legal Protections for Participants in Genomic Research*, 29 HEALTH MATRIX 1, 98 (2019).

141. See Check et al., *supra* note 34, at 3 (noting that once information is placed in the medical record, it is no longer protected by a Certificate of Confidentiality).

HIPAA.¹⁴² If these limitations of Certificates of Confidentiality and HIPAA are not clearly noted in the consents of studies that place research results in medical records, participants may have a false sense as to the confidentiality of their information and make a decision to join a research study that they would not otherwise have if the information had been provided.

VI. DISCLOSING PRIVACY AND DISCRIMINATION PROTECTIONS IN PRACTICE

There is a myriad of complex privacy and anti-discrimination information that individuals may find important to their decision whether or not to join a research study. As the previous section shows, research projects include both unintended and anticipatable information sharing that may be significant to individuals. Descriptions about legal protections and gaps may be necessary to understand the likelihood of any risks associated with information sharing being realized.¹⁴³

However, empirical research shows not only that information about privacy and discrimination laws may be important to an individual's decision to join a study, but that how these protections are described could impact individuals' assessments of the risks and benefits of research.¹⁴⁴ Specifically, providing greater detail about limitations of legal protections in informed consent is likely to lower individuals' willingness to participate in the research study.¹⁴⁵ Thus, under a reasonable participant standard, it is arguable that all information about limitations of a law should be disclosed since it impacts decisions of joining studies. However, this task would quickly make informed consent documents unwieldy and impractical. This leads to a Goldilocks conundrum—what is the balance to disclose just the right amount of information about non-medical privacy or discrimination risks and their associated legal protections?

142. *See, e.g.*, Mark A. Rothstein, *Currents in Contemporary Bioethics: Access to Sensitive Information in Segmented Electronic Health Records*, 40 J. L. MED. & ETHICS 394, 396 (2012).

143. *See supra* Section V.C.

144. *See supra* Section III.

145. *See supra* Section III (summarizing the findings of Prince et al., *supra* note 38).

This section helps to answer this question by highlighting the competing harms of both under and over disclosure of legal protections and discussing how contextualization of risk information can help to balance between the two extremes. However, given that individual contextualization of risk is a complex task that often requires legal expertise, it is best for this contextualization to occur at the study population level with the aid of IRBs.

A. Balancing between Under and Over Disclosure

Respect for autonomy necessitates that individuals should be informed of the risks and benefits of research. Yet, presenting too much information about risk potentially diminishes the goals of informed consent because it could diminish comprehension, focus too much on risks unlikely to actually occur, or overwhelm individuals.

1. Harms of Too Little Disclosure

Legal standards require that researchers disclose any information that would affect the decision of a reasonable participant.¹⁴⁶ As this paper has shown, this includes information about privacy and discrimination laws, but also their limitations. The limitations are important because, in some cases, inclusion of such information is recommended by OHRP, but also, as the empirical GINA study makes clear, learning about the limitations of the law can affect willingness to participate in a hypothetical research study.¹⁴⁷ Therefore, under a reasonable participant standard, it is logical to err on the side of more comprehensive disclosure of privacy and anti-discrimination protections and limitations. Real-world evidence also suggests that research participants make decisions about joining studies based on privacy or anti-discrimination protections, especially in the context of genetic research.¹⁴⁸ Thus, if informed consent

146. 45 C.F.R. § 46.116(a)(4) (2018).

147. *See supra* Section III at 9.

148. Laura M. Amendola et al., *Why Patients Decline Genomic Sequencing Studies: Experiences from the CSER Consortium*, 27 J. GENETIC COUNSELING 1220 (2018); Robinson et al., *supra* note 135, at 26; *but see* Clayton et al., *supra* note 90, at 9 (highlighting that some individuals feel more comfortable after receiving information about GINA because they feel more protected).

documents only cursorily discuss privacy and anti-discrimination protections without describing the nuanced limitations of the laws, individuals may be agreeing to undertake research that they would not otherwise have if they had been fully informed.

Another potential harm of too little disclosure is that individuals may feel overly assured about their protections if nuance and limitations of legal protections are not fully enumerated.¹⁴⁹ For example, in a study exploring disclosure of protections regarding Certificates of Confidentiality, IRB professionals voiced concerns that describing protections of the certificates could overly reassure participants if the nuances of the protections were not adequately described.¹⁵⁰ Similar themes arose in the empirical GINA work described above. In some instances, those individuals who received the Basic Disclosure assumed that there were no risks of discrimination by life insurers or other actors because they were not mentioned in the consent language.¹⁵¹ Thus, individuals may assume that researchers will disclose all relevant discrimination risks in informed consent documents and thus, if not explicitly disclosed, will incorrectly conclude that they are more protected than they actually are. Many individuals consent to studies because they trust the researchers who are conducting the study,¹⁵² and this may increase the likelihood that they trust the researcher to tell them all relevant information about risks.

2. Harms of Too Much Disclosure

However, if we take seriously the proposition that the reasonable participant standard demands that information about both legal protections and limitations be included in informed consent, the consent documents could get long and unwieldy very quickly. This is especially true given the wide range of privacy and anti-discrimination related information that is relevant in research that involves big data, AI, translational research, or

149. OHRP Guidance, *supra* note 6, at 6; Check et al., *supra* note 34, at 6.

150. Check et al., *supra* note 34, at 6.

151. Prince et al., *supra* note 38, at 6.

152. Botkin, *supra* note 82, at 83; *see also*, Platt et al., *supra* note 105, at 8 (arguing that failing to disclose information about secondary research requires individuals to place trust in biobanks).

genetic sequencing.¹⁵³ Two primary potential harms can arise from this overload of information.

First, there is ample evidence that individuals rarely fully read informed consent documents and often appreciate little about studies or procedures to which they have consented.¹⁵⁴ For example, one systematic review of informed consent in surgery found that people adequately understood important aspects of the research approximately 50% of the time.¹⁵⁵ Adding too much additional information could make it even less likely that individuals will read and comprehend the information. Therefore, there are arguments that consent documents should be streamlined to focus on risks that are more likely to occur or be more serious if they do occur.¹⁵⁶ Indeed, one goal of the revised Common Rule was to encourage researchers to create informed consent documents that are organized in a way to best facilitate participants' understanding of the reasons for and against joining

153. *See supra* Section V.A. at 26.

154. James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292 J. AM. MED. ASS'N 1593, 1593 (2004) (describing a variety of research showing limited comprehension of informed consent documents).

155. Matthew E. Falagas et al., *Informed Consent: How Much and What do Patients Understand?*, 198 AM. J. SURGERY 420 (2009).

156. There are some arguments that this is what individuals expect from informed consent documents across many different types of risk. "It is natural to expect that a clinician would disclose common, non-trivial risks of a procedure and so natural to infer that the risks disclosed comprise at least all the ones that are common and non-trivial." Millum & Bromwich, *supra* note 70, at 52.

the study.¹⁵⁷ However, presenting information in ways that actually achieves participant comprehension is difficult.¹⁵⁸

Second, providing too much information to individuals could have the potential to overwhelm them, either emotionally or through information overload.¹⁵⁹ Individuals could be emotionally overwhelmed because of the medical reality that brought them into research in the first place,¹⁶⁰ or the risk information itself could be presented in a way that leads to additional anxiety or apprehension about the study being consented to.¹⁶¹

If the actual underlying privacy or discrimination risk is low, the anxiety caused by worrying about a lack of robust legal protections could be more harmful than the actual privacy and

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157. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7213 (Jan. 19, 2017) (to be codified at 49 C.F.R. pt. 11); 45 C.F.R. § 46.116(a)(ii) (2018) (“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”); *but see* Evan G. DeRenzo et al., *Implications of the Revised Common Rule for Human Participant Research*, 155 CHEST 272, 275 (2019) (arguing that the efforts at increasing participant understanding may not actually lead to more effective or more useful consent documents).
158. *See generally* Laura M. Beskow & Kevin P. Weinfurt, *Exploring Understanding of ‘Understanding’: The Paradigm Case of Biobank Consent Comprehension*, 19 AM. J. BIOETHICS 6 (2019) (raising the question of which elements of consent must be truly understood in order to join a study after research reveals that some participants do not comprehend essential aspects of the consent).
159. Johan Bester et al., *The Limits of Informed Consent for an Overwhelmed Patient: Clinicians’ Role in Protecting Patients and Preventing Overwhelm*, 18 AM. MED. ASS’N J. ETHICS 869, 871 (2016).
160. *Id.* at 875–76.
161. *Salgo v. Leland Stanford Jr. University Board of Trustees*, 154 Cal. App. 2d 560, 578 (1957); *see also* Check et al., *supra* note 34, at 6 (noting that the same disclosed information could raise anxiety when presented in different research contexts, using the example that information about how Certificates of Confidentiality provide protections for legal jeopardy may be comforting in a study about illegal behavior, but may be alarming in a study with a simple blood draw).

discrimination risks itself. For example, in the empirical work presented in this paper, shows that those receiving the Comprehensive Disclosure had, on average, greater fear of discrimination than those receiving the Minimum Disclosure.¹⁶² However, the actual risk of discrimination in property insurance, education, or other areas disclosed in the Comprehensive Disclosure may be quite low. Therefore, over-disclosure of risks could potentially lead to unnecessary fear or anxiety about future harm.

Perhaps especially in the context of complicated and nuanced legal information about privacy and discrimination risks, individuals could experience information overload.¹⁶³ “A patient’s ability to provide informed consent may also be overwhelmed by the complexity, uncertainty, or volume of information involved in the decision, as may occur with the emergence of new technologies such as whole genome sequencing.”¹⁶⁴ In some cases, too much information can arguably affect the individual’s capacity to make decisions.¹⁶⁵

B. Assessing Privacy and Discrimination Protections

One way to balance between under- and over-disclosure of privacy and discrimination legal protections and limitations is to only provide information that is directly relevant to the individual, thus more closely adhering to a subjective standard of consent.¹⁶⁶ However, a true understanding of what privacy or discrimination risks an individual might be facing often requires nuanced legal analysis. In general, when an attorney is assessing potential risks of harm to a client, such as privacy risks or risks

162. *See supra* Section III, at 14.

163. *See, e.g.*, Check et al., *supra* note 34, at 5 (quoting an IRB chair as saying that they did not include information included in the NIH’s recommended language on Certificates of Confidentiality because it was “way more than people need to know”. In particular this person was worried that the added details could “detract from the main point of the Certificate description”).

164. Bester et al., *supra* note 159, at 876.

165. *Id.*; *see also* FADEN & BEAUCHAMP, *supra* note 1, at 323 (noting that “[f]rom the perspective of substantial understanding, information overload can be as significant as information underload”).

166. *See supra* Section IV.A.2.

for discrimination, there are three broad steps they must complete: 1) identify the primary legal protections and laws; 2) identify gaps in these protections; and 3) contextualize the legal protections to an individual's specific situation.¹⁶⁷ This can be an incredibly complex analysis depending on the circumstances, raising issues of state/federal preemption, choice of law, legal interpretation and differences in enforcement mechanisms.¹⁶⁸ Given this complex analysis, a question arises as to how much of this process must researchers complete and communicate to prospective participants in order to achieve truly informed consent and, whether the researchers have proper expertise to undertake this analysis and disclosure in the first instance.

1. Contextualization

To holistically understand potential privacy and discrimination risks that an individual may be taking on, there needs to be an understanding, not just of legal protections and the potential limitations, but also some contextualization of how these protections apply to an individual's particular situation and the likelihood that the risk will be actualized. For example, in the context of genetic discrimination, many different personal and societal factors contribute to individual risk of genetic discrimination. Take two individuals considering enrolling in a genomic research study about breast cancer. One is a 70-year old retiree who is a breast cancer survivor herself. She lives with her partner and has step-children and grandchildren, but no biological children of her own. She currently has a whole life insurance policy that she purchased decades ago and is on Medicare. The other is a 25-year old graduate student. She is adopted, so does not know her family history of breast cancer and thought it would be interesting to learn about her potential risk. The student is on her parent's health insurance plan and has no life insurance or other insurances. She hopes to secure benefits through her job once she graduates at the end of the year. She

167. See generally FREDERICK SCHAUER, *THINKING LIKE A LAWYER: A NEW INTRODUCTION TO LEGAL REASONING* (Harvard Univ. Press 2009) (detailing the steps involved in legal reasoning).

168. See, e.g., *Direct-to-Consumer Genetic Testing: The Law Must Protect Consumers' Genetic Privacy*, CONSUMER REPORTS (July 2020) (mapping the complexity of state and federal laws related to genetic testing and noting issues of enforcement and choice of law).

and her partner are also talking about starting a family in the next five years.

While the informed consent document would likely include the same information about the risks of genetic discrimination, the actual risks for each of these women are widely different. The retiree is clearly not at risk of employment discrimination and, given that she does not have any biological children, any genetic results would not have implications for the employment or insurance of her immediate family members. It also appears that she has adequate life and health insurance, so whether and how these insurances can legally use genetic information is less of a concern. Finally, as a cancer survivor herself, this diagnosis is likely to be much more relevant to any potential insurer, such as a long-term care insurer, than a genetic predisposition to cancer.

In contrast, genetic discrimination is likely a greater risk for the graduate student. Since she does not yet have employment and insurance, it is important for her to know how a potential genetic finding could impact these endeavors. Additionally, even if she were already working at a larger company, at 25, the chances of moving jobs or careers is relatively high, so she may want to know about GINA's lack of protections for small businesses. Additionally, she may be more interesting in learning about the gaps of GINA as it relates to entities beyond life, long-term care, and disability insurers, since these companies may increasingly use genetic information as she grows older and seeks mortgages or property insurance. Finally, she may want to know about how legal protections could impact her family in the future.

At first blush it may seem like a hefty task for researchers to even begin to contextualize informed consent to meet the informational needs of specific individuals; however, this is a common element in informed consent disclosures of medical risk. For example, in one list of necessary elements of informed consent, a legal handbook recommends the disclosure of: "any increase in risk due to presence of special risk factors in the patient."¹⁶⁹

169. DAN J. TENNEHOUSE, 1 ATTORNEYS MEDICAL DESKBOOK § 10:11. Lack of Informed Consent (2022) (The desk book goes on to give an example of this requirement. "For example, the patient has a known history of alcoholism and is found to have active tuberculosis. Initial laboratory tests show no liver abnormalities, and the physician decides to start the anti-tuberculosis drug isoniazid. The physician does not mention that on rare occasions

Yet, how much should the presence of ‘special risk factors’ of individuals in the context of privacy and discrimination risks come into play? Relatedly, how much of this contextualization should be the responsibility of the researcher versus the individual themselves?¹⁷⁰ Although it is clear from the above example that the graduate student is at higher risk for genetic discrimination than the retiree, actually quantifying the likelihood of this risk in light of existing legal protections is still extremely difficult. Additionally, there is a lack of data showing widespread genetic discrimination in employment or insurances,¹⁷¹ so contextualizing the likelihood of risks even absent legal protections is tricky. Finally, it is important to keep in mind that, beyond potential for discrimination, the potential impact of loss of privacy could differ across individuals based on how their subjective feelings about potential breaches in privacy as a dignitary concern.¹⁷²

The complexity and uncertainty of contextualizing privacy and discrimination risks in light of legal protections carries

isoniazid can cause severe and sometimes fatal hepatitis. There may be no general duty to disclose this risk because isoniazid hepatitis is rare. However, isoniazid hepatitis occurs considerably more frequently among chronic alcoholics. The presence of the alcoholism risk factor probably creates a duty of disclosure of the hepatitis risk, and probably also requires that the physician explain to the patient the extent of the increased risk”).

170. It is clear that at least some participants themselves contextualize risk information based on their own situation. Thus, what the individual finds relevant to their decision may depend upon the contextualization. Clayton et al., *supra* note 90 (highlighting that empirical studies found that some individuals felt less concerned about employer or insurance access to genetic information because of their own personal situation). This trend was supported by findings from the empirical GINA study. Prince et al., *supra* note 38 (describing qualitative results that show that some individuals were less concerned with discrimination because of their personal situations).
171. See Clayton et al., *supra* note 90. This has been true historically as well, even pre-GINA. See, e.g., Sharon J. Durfy et al., *Testing for Inherited Susceptibility to Breast Cancer: A Survey of Informed Consent Forms for BRCA1 and BRCA2 Mutation Testing*, 75 AM. J. MED. GENETICS 82, 86 (1998).
172. See, e.g., Clayton et al., *supra* note 90, at 12–14 (noting that studies have shown that privacy concerns vary by race or ethnicity, age, religiosity, and political affiliation).

beyond just genetic discrimination concerns to other potential privacy and discrimination harms. With other privacy and discrimination concerns, the risks are similarly difficult to identify the likelihood,¹⁷³ potentially quite low,¹⁷⁴ or the harms are dignitary and thus difficult to quantify.¹⁷⁵ Furthermore, there may be future changes to the law that greatly affect individuals' privacy risks.¹⁷⁶ However, being able to contextualize risks to individual circumstances has the potential to minimize some of the concerns of over-disclosure, such as increasing anxiety based on limited actual risk. Thinking back to the example of the retiree and grad student joining a genetics study, if risks and legal protections were contextualized, less information about potential privacy risks would need to be disclosed to the retiree, thus limiting the chances of her being overly concerned about risks that are unlikely to actualize.

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173. See Check et al., *supra* note 34, at 5 (noting that Certificates of Confidentiality have not been tested in court, so it is unclear how well they protect against potential harms).
174. See, e.g., Henderson, *supra* note 103, at 263 (describing how threats to privacy and confidentiality of genetic data obtained from 23andMe is likely quite low within broad data sharing because the data is de-identified and stored using security procedures); see also Clayton et al., *supra* note 90, at 3 (noting that there is little evidence of efforts to re-identify de-identified individual data other than for proof of principle studies and that such attacks may be unlikely for practical reasons).
175. Clayton et al., *supra* note 90, at 2.
176. For example, while GINA and the Affordable Care Act (ACA) each provide protections in health insurance and access to coverage, there have been political efforts to repeal these laws or to water down their protections. See, e.g., American Health Care Act of 2017, H.R. Res. 1628, 115th Cong., 1st Sess. (2017), (memorably voted down in 2017 after a deciding vote by Senator John McCain: see, e.g., Susan Davis & Domenico Montanaro, *McCain Votes No, Dealing Potential Death Blow to Republican Health Care Efforts*, NPR (July 27, 2017 11:46 PM) <https://www.npr.org/2017/07/27/539907467/senate-careens-toward-high-drama-midnight-health-care-vote> [<https://perma.cc/G6AL-T8KE>]). Preserving Employee Wellness Programs Act, H.R. Res. 1313, 115th Cong., 1st Sess. (2017).

2. Expertise

Contextualizing privacy and discrimination risks may be important for individuals to be truly informed of risks and to help avoid over-disclosure of elements of the law that may unduly produce anxiety or lead to information overload for those who do not need this information. However, contextualizing risk also requires legal analysis that may be beyond the expertise of those consenting the researchers. This concern over expertise has similarly been raised in the clinical context: “[p]hysicians are not sociologists, economists, theologians, or philosophers . . . and it is implausible to conclude that the Legislature intended that physicians be required to venture far beyond their professional specialty and expertise to advise patients of nonmedical matters such as the social or economic risks”¹⁷⁷ Similarly, researchers are often scientists or social scientists who will not have the robust legal background to understand how to begin to identify relevant legal protections, let alone their gaps and implications for a particular individual. What’s more, too much analysis of how legal protections apply to individualized circumstances, if discussed in detail with the participant, could raise concerns about the unlicensed practice of law.¹⁷⁸

C. The Role of Institutional Review Boards

It is clear that a reasonable participant may desire disclosure of a broad range of privacy and discrimination risks and their associated legal protections. However, while this may be true in theory, in practice there are concerns about how to draw a

177. Sawicki, *supra* note 5, at 847 (quoting *State v. Presidential Woman’s Ctr.*, 937 So. 2d 114 (Fla. 2006))(internal quotations omitted); *see also* *Clark v. Grigson* 579 S.W.2d 263, 265 (Ct. Civil App. Dall., Tex.) (1979) (finding that the physician did not need to disclose the possibility of adverse testimony in a criminal trial stemming from a psychiatric evaluation because this was a more appropriate disclosure for a patient’s attorney).

178. This concern has likewise been raised in other healthcare contexts where non-lawyers are assessing the legal circumstances of an individual. *See, e.g.*, Anya E.R. Prince & Arlene M. Davis, *Navigating Professional Norms in an Inter-Professional Environment: The ‘Practice’ of Healthcare Ethics Committees*, 15 CONN. PUB. INTEREST L. J. 115 (2016) (discussing times when the work of healthcare ethics committees could implicate the practice of law).

limiting principle in order to avoid over-disclosure of every last limitation in a particular privacy law. One possible way to balance between under- and over-disclosure is to contextualize the privacy and discrimination risks and protections to a particular participant. This strategy is employed in the context of medical risks in consent, but it raises issues around the complexities of contextualizing legal protections in practice and concerns about the expertise of those doing the consenting. These concerns can be minimized by turning the locus of analysis from the individual to the study population and from the researcher to the IRB.

IRBs are federally mandated review boards that are tasked with overseeing that proposed research protocols are ethical and compliant with federal regulations, such as the Common Rule.¹⁷⁹ One of the core tasks of IRBs is to assess the risks and benefits of a proposed research study to ensure that the risks are minimized and reasonable in relation to the anticipated benefits of the study.¹⁸⁰ They also review informed consent documents.¹⁸¹ IRBs can help to provide a limiting principle on disclosure of privacy and discrimination information by facilitating contextualization of the legal protections and limitations to the study population.

Overall, IRBs should assist researchers to answer the following questions related to privacy and discrimination risks:

- What legal protections are necessary to disclose given the potential unintended and anticipatable information sharing related to the project? (including any state laws)
- Which privacy and discrimination risks would be most significant to or likely for the research participant population?

179. Christine Grady, *Institutional Review Boards: Purpose and Challenges*, 148 CHEST 1148, 1148 (2015). IRBs are required for studies funded by the U.S. Department of Health and Human Services and for research under the purview of the Food and Drug Administration, however research institutions often require all human subjects research to undergo IRB review. *Id.*

180. *See id.* at 1149; 45 C.F.R. § 46.111 (2022).

181. Grady, *Institutional Review Boards: Purpose and Challenges*, *supra* note 179, at 1149. In some instances, the IRB can approve a waiver of consent instead of an approval of the written informed consent document. 45 C.F.R. § 46.116(f) (2022).

- Are there any known special risk factors in this research participant population that necessitate disclosure of a particular legal protection and/or its limitation?

To be fair, many IRBs engage in these types of analyses with researchers every day. However, given the growing complexity of information sharing and privacy risks and empirical evidence that shows that reasonable participants may be interested in greater detail about a law's limitations than standard disclosures include, it may be appropriate to revisit disclosure regarding privacy and discrimination laws and gaps. This is especially important in the context of standardized or boilerplate language that is used across a wide variety of studies.

1. Identification of Legal Protections

Identifying pertinent legal protections is a key step in assessing the likelihood that privacy or discrimination risks may be actualized.¹⁸² While identifying relevant legal protections can require complex and nuanced analysis, IRBs are better equipped than researchers to undertake this task for several reasons.

First, because IRBs are already tasked with assessing regulatory and legal compliance, they are more likely than researchers to have the expertise—or, at the very least access to individuals with expertise—to assess privacy and discrimination laws.¹⁸³ For example, the Common Rule requires that IRBs, through the experience and expertise of its members, be sufficiently qualified to assess compliance with regulations and applicable law.¹⁸⁴ While this is not exactly the same as having wide-ranging expertise regarding privacy and discrimination laws, it does mean that IRBs are likely to have greater expertise in the area than general researchers. Additionally, the IRB can

182. *See supra* Section V.C.

183. *See, e.g.,* Benjamin S. Wilfond et al., *The Limitations of “Boilerplate” Language in Informed Consent: Single IRB Review of Multisite Genetic Research in Military Personnel*, 19 AM. J. BIOETHICS 81, 82 (2019) (noting that in one instance, an IRB felt that standardized language in consents was insufficient for a particular study population, but was uncertain how to best describe protections, so they undertook an ethics consultation to help them address the issue).

184. 45 C.F.R. § 46.107(a) (2022).

collaborate with institutional partners such as general counsel officers, subject matter experts, or external advisors more easily than each individual research study.

Second, because IRBs see many different research proposals, they are likely to see similar data sharing and informational risks across a wide-range of projects. Thus, they will be more likely to be able to identify which types of legal protections are implicated by a particular study design after reviewing with experts various proposals and laws at the federal and state level.

2. Assessment of the Likelihood of Privacy and Discrimination
Risks

Once the informational risks and overarching legal protections are identified, IRBs can help to assess the likelihood of the privacy and discrimination risks for participants, in light of the legal protections and gaps. An existing core task of IRBs is to assess the risks of any proposed study.¹⁸⁵ An initial threshold question that IRBs must assess is whether a study presents more than a ‘minimal risk’.¹⁸⁶ Defining a study as only involving minimal risks has implications for the type of IRB review it must undergo.¹⁸⁷ Minimal risk is defined as, when “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”¹⁸⁸

While assessment of privacy and discrimination risks already occurs within the IRB setting, the function of assessing the

185. NRC Proposed Revisions, *supra* note 91, at 59 (describing the Common Rule, and thus, by implication, the role of IRBs, as a “risk-based rubric”).

186. 45 C.F.R. § 46.102(j) (2022).

187. 45 C.F.R. § 46.110 (2022).

188. NRC Proposed Revisions, *supra* note 91, at 60; This definition has been critiqued for several reasons, including that it is difficult to interpret because it is unclear whether it should be the daily life of the general public or the daily life of someone within the study population. *Id.* at 61. There are concerns, however, that defining the assessment of minimal risks as compared to that faced by the study population could cause an unjust distribution of risks since some study populations naturally face greater risks in daily life and thus would be subjected to greater risks in studies. *Id.*

likelihood of risks for purposes of informed consent disclosure is different than for purposes of assessing minimal risk for approving a study. “Risk is a word fraught with many connotations, and the way the word is used in a lay context does not necessarily equate with that used in the utilitarian cost-benefit analysis intended by the Common Rule.”¹⁸⁹ Thus, since the role of informed consent is to disclose risks that a reasonable participant would want to know, risk in informed consent should arguably encompass a more lay interpretation than a calculus to determine compliance with the Common Rule.¹⁹⁰ In other words, an IRB could find that a certain privacy risk would constitute minimal risk, but should still be disclosed in an informed consent document to allow participants to make an autonomous choice about taking on this risk. As shown by the empirical evidence presented in this paper, this may involve disclosure of the nuanced gaps in legal protection.

In a commentary on the Common Rule Notice of Proposed Rule-Making (NPRM), the National Research Council recommended that OHRP guidance should “clarify for IRBs that informed consent does not include risks and benefits low in magnitude and low in probability. Description of potential research risks and benefits should be limited to those that might *reasonably* occur and those risks that would cause substantive harm if they occurred.”¹⁹¹ This recommendation fits neatly into existing practices within the privacy and data security communities and thus could be effectively employed for assessment of privacy and discrimination risks for purposes of informed consent development. For example, the National

189. *Id.* at 59 (internal quotations omitted).

190. Another example is that while minimal risk should be assessed in reference to risks faced by the general population, *Id.* at 61–62, risks for purposes of informed consent should be assessed in reference to the study population. *See infra* Section VI.C.3.

191. NRC Proposed Revisions, *supra* note 91, at 99. The Common Rule does not specifically define risk, absent reference to minimal risk, although early OHRP guidance notes that risk can be assessed by both the probability and magnitude of possible harm. *Id.* at 59. However, determining how to assess both the probability and magnitude of a possible harm can be challenging and sometimes IRBs have focused more on the magnitude of the potential harm than the probability. *Id.* at 63, 66.

Institute of Standards and Technology (NIST) in the U.S. Department of Commerce has recently developed a privacy framework to help companies adequately protect individual privacy.¹⁹² A key feature of the framework is the privacy risk assessment, which is a process for “identifying and evaluating specific privacy risks”.¹⁹³ The privacy risk assessment is meant to identify various privacy risks and to quantify the risk based on the likelihood of the harm multiplied by the impact of the harm.¹⁹⁴

Thus, IRBs can leverage expertise and knowledge within the data privacy and security community to conduct in-depth privacy assessments for research studies using existing methods within the data security community.¹⁹⁵ This can help to identify key privacy risks that are both likely and impactful for research participants, in light of existing legal protections and limitations. Those that are found to be unlikely and low impact would not need to be disclosed in informed consent documents, thus helping to minimize concerns of over-disclosure of legal protections and limitations.

One danger with this framework is that researchers and IRBs focus too much on assessing and subsequently disclosing

192. U.S. DEP’T OF COM.: NAT’L INST. OF STANDARDS AND TECH., NIST PRIVACY FRAMEWORK: A TOOL FOR IMPROVING PRIVACY THROUGH ENTERPRISE RISK MANAGEMENT i, (2020) [hereinafter NIST Privacy Framework].

193. *Id.* at 4.

194. *Id.* at 35.

195. As the NIST Privacy Framework mentions, there are many different methods for conducting privacy assessments, but the NIST has adopted the Privacy Risk Assessment Methodology (PRAM) as one way to conduct assessments. *Id.* at 35 n. 19. Some of this analysis, especially with regards to federal laws, could be completed by HHS. For example, the NPRM draft of the Common Rule required the Secretary of HHS to develop a list of research activities that would count as minimal risk. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7172 (Jan. 9, 2017) (to be codified at 45 C.F.R. 46). While this recommendation was not codified into the final rule, the discussion of the final rule still encouraged this to be done as a separate process. *Id.* Thus, if HHS undertakes review of study activities that could be considered minimal risk, they will have an opportunity to deeply assess how privacy and discrimination risks come into play in these assessments.

protections related to unintended information disclosures, but do not fully evaluate or disclose protections related to anticipatable information disclosures.¹⁹⁶ Assessment of the risks of unintended information sharing is very much dependent upon the data security measures adopted by research teams and are important to disclose. However, as the NIST framework makes clear, there is overlap, but distinction between data security or cybersecurity risks and other privacy risks.¹⁹⁷ IRBs and researchers should simultaneously and thoroughly assess the privacy risks of anticipatable privacy harms, especially since this is where the limitations of legal privacy and discrimination protections are most likely to come into play.

Finally, because the goal of assessment of risks for purposes of informed consent disclosure is so intertwined with how a reasonable participant will view the risks, it is important to bring in the viewpoints of the study population as much as possible. For example, community advisory boards (“CABs”) that are either associated with a research study or entity could be consulted for advice regarding the level of detail about legal protections and limitations that would be relevant for a particular study population.¹⁹⁸

196. For example, in their discussion of the need to assess both the magnitude and probability of risks, the NRC notes that it is difficult to assess the probability of information disclosure, but only speaks of unintended risks of failing to adequately secure research data or re-identification of de-identified data. It does not grapple with how to assess the probability and magnitude of anticipatable disclosures. NRC Proposed Revisions, *supra* note 91, at 113–14 (defining informational risk as “the probability of harm of storing, using, and reporting on research data, multiplied by the magnitude of the harm from unintended release”).

197. NIST Privacy Framework, *supra* note 192, at 3.

198. Philip G. Day et al., *Utilizing Community Research Committees to Improve the Informed Consent Process*, 21 AM. J. BIOETHICS 73, 74 (2021) (highlighting how inclusion of community members can improve the informed consent process); *see also* DeRenzo et al., *supra* note 157, at 274–75 (noting that IRBs can increase competency by seeking the viewpoints of those with specialized expertise or advocacy backgrounds related to the study population). This can also be helpful to provide perspectives on how participants conceptualize privacy harms to begin with. For example, Rotimi & Marshall recommend that “[b]efore initiating a study, researchers should consider what confidentiality, privacy,

3. Contextualization to the Study Population

It is difficult to assess, at the individual level, how each potential participant's circumstances might affect the likelihood that privacy or discrimination harms would occur. Indeed, the informed consent documents for any particular research study will already be written before any potential participant is recruited. Thus, researchers may not know the individualized concerns or special risk factors of an individual while developing the written informed consent document.¹⁹⁹ In addition to the concerns of complexity, expertise, and practice of law discussed above,²⁰⁰ this makes individualized contextualization of privacy and discrimination risks impractical in informed consent.

However, researchers will know the key features of the study populations that they are seeking to recruit as informed consent documents are being developed. Thus, researchers and IRBs should ensure that consent documents, particularly the description of privacy and discrimination protections and limitations, are contextualized to the study population.²⁰¹ For

and 'secrecy' mean to study participants who may bear the burden of stigmatization or discrimination, and should apply this knowledge in developing the consent process." Rotimi & Marshall, *supra* note 40, at 4.

199. There would arguably be more chance for individualized descriptions during the entire informed consent process, which includes conversations between perspective participants and a member of the research team. However, this raises similar, if not even starker, concerns of expertise than individualized written consents.

200. *See supra* Section VI.B.

201. This is particularly necessary when discussing privacy protections. *See, e.g.*, Sara Chandros Hull & Adam I. Schiffenbauer, *Single IRBs Are Responsible to Ensure Consent Language Effectively Conveys the Local Context*, 19 AM. J. BIOETHICS 85 (2019) (noting that "privacy protections . . . are complex and context dependent"). Additionally, altering study features and informed consent to best meet the needs of a particular study population has been suggested in other contexts before. *See, e.g.*, Rotimi & Marshall, *supra* note 40, at 1–2 (arguing that in research involving ethnically, socio-economically and linguistically diverse study populations, informed consent documents should be tailored with consideration of ten factors); DeRenzo et al., *supra* note 157, at 274–75 (arguing that special protections can be incorporated into research protocols to meet the needs of vulnerable populations and

example, if a genomics research study is enrolling adults older than age 65, they may not need to disclose as much information about some of the limitations of GINA since the study population is more likely to be retired or face less risk of insurance discrimination based on their genetic information.²⁰² This is intertwined with the privacy assessment analysis described above since, in this example, the likelihood of information sharing may be the same across study populations, but the magnitude of impact of harm would vary depending upon the situation given that different study populations may be more likely to be impacted by limitations in the law.

It is well within an IRB's purview and daily practice to undertake such contextualization. For example, the OHRP GINA guidance specifically notes that "IRBs should feel free to revise the sample language above as appropriate based on the nature of the research and the types of human subjects involved."²⁰³ Additionally, it is recommended that IRBs take into account contextual features of the research study, including unique characteristics of the population being studied.²⁰⁴ It is also clear that IRBs often do take these factors into account when approving informed consent language.²⁰⁵

Yet such contextualization does not always currently occur, especially when boilerplate or standardized language is used in consent forms, such as those developed for GINA and Certificates of Confidentiality.²⁰⁶ Additionally, there are institutional barriers that create challenges for IRBs to alter privacy and discrimination language.²⁰⁷ Notably, standard language "is

noting that informed consent documents may need to be reworked for populations with lower reading proficiency).

202. See *supra* Section VI.B.1.

203. OHRP Guidance, *supra* note 6.

204. Hull & Schiftenbauer, *supra* note 201, at 85.

205. See, e.g., Botkin, *supra* note 82, at 84.

206. Wilfond et al., *supra* note 183, at 81 (noting that sometimes boilerplate consent language is included in documents "even if it does not clearly make sense in the context of a specific study").

207. In addition to the barriers discussed in this section, it is important to note that contextualization of legal risks to study populations gets increasingly difficult as the size and diversity of a study grows. For example, national studies seeking to enroll participants from a

typically fixed, and has often been fully and painstakingly negotiated and vetted by multiple parties (e.g., privacy officer, general counsel, genetic researcher stakeholders, the IRB, research management, medical records management, and others).²⁰⁸ Thus, changes to consent language for a particular study could require reengaging these various stakeholders.²⁰⁹ It is often the descriptions of the legal protections, notably the privacy and discrimination protections, that are more likely to have requirements to put them in consents without changes to the language since they have been written by lawyers at the institutions.²¹⁰ These institutional barriers, however, should not prevent IRBs from providing participants with clear information that is relevant for their autonomous decision-making.²¹¹ This contextualization is essential to respect the reasonable participant and ensure that they are provided with nuanced and appropriate information about privacy and discrimination protections and limitations during informed consent.

wide variety of backgrounds will likely find it difficult to narrow the relevant laws in a meaningful way. *See, e.g.*, Wolf et al., *The Web of Legal Protections for Participants in Genomic Research*, *supra* note 140, at 59 (“In a national study like the All of Us project, the multiplicity and variation of state laws mean some participants may have legal protections and rights that other participants do not. This raises challenging questions for IRB review and consent form drafting. How does the IRB appropriately assess the risk/benefit ratio for the study in the review process? And how does the consent form communicate the different protections afforded to participants?”). Additionally, research projects with multiple sites will run into complexities negotiating across populations or, potentially, IRBs. *See generally* Wilfond et al., *supra* note 183, at 82; Melissa E. Abraham et al., *Solving the Single IRB/Boilerplate Bind: Establishing Institutional Guidelines*, 19 AM. J. BIOETHICS 87, 87-88 (2019); Hull & Schiftenbauer, *supra* note 201, at 85.

208. Abraham et al., *supra* note 207, at 87.

209. *Id.*

210. Botkin, *supra* note 82, at 83.

211. *See id.* at 84.

VII. CONCLUSION

Historically, when an individual participated in research, many of the potential associated risks were medical. A participant in a clinical trial may have worried about unanticipated side effects of a medication. An enrollee in a study on cancer may have worried that the procedure to biopsy the tumor would be harmful. The greatest non-medical risks were likely privacy related, such as if the participant's identity was disclosed beyond the bounds of the experiment, particularly if this revealed a particular medical diagnosis. Today, growing use of technology, big data, and broad data sharing practices increases the privacy and discrimination risks of research studies while often limiting the medical risks. Thus, clearly disclosing what an objective research participant would want to know about privacy risks regarding the study is important. However, while it is clear that researchers must disclose everything the reasonable person would want to know when making the decision, delineating clear boundaries of necessary information is more difficult.

Research participants should be, and often are, at least to some extent, told of the foreseeable risks of their information being shared—whether that sharing is unintended or anticipable. However, for participants to truly understand the risk of loss of privacy and potential for discrimination that flows from these information disclosures, they arguably must have a robust understanding of both when and how information may be shared, but also the legal protections and limitations that govern use of that data.

Disclosing this vast array of information about legal protections and limitations in practice may lead to problematic over-disclosure. One option for balancing between under and over disclosure of privacy and discrimination risks is to contextualize the harms for each participant. This however is impractical in practice given the complexities of contextualizing legal protections and concerns about the expertise of those doing the consenting. Instead, rather than focusing on individual participants and researchers, the contextualization and assessment of privacy and discrimination laws and limitations should occur at the level of the study population with input from IRBs. This will help to provide sufficient information about privacy and discrimination protections and their limitations that helps study participants to understand risks and practice

autonomous decision-making while narrowing the disclosures to those likely to be most relevant and impactful for study participants.