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Putting the L in ELSI: legal methods for bioethics research

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ABSTRACT

Lawyers and law professors are increasingly involved in interdisciplinary scientific teams and grant research to answer ethical, legal and policy questions related to biomedical topics. Yet, the methods that lawyers use to conduct legal research and analysis are not always familiar to scientists and social scientists conducting peer review of a proposed project with legal aims or a publication reporting a legal study. To better facilitate interdisciplinary ethical, *legal*, and social implications collaboration, there is a need to better explain how legal research methodologies can provide robust tools to address a range of nuanced biomedical questions. This paper explores legal research and analysis methodologies relevant to federally funded research and scientific inquiry. It sets out different ways that legal research and analysis can advance and support biomedical, bioethics, and health law research

and then demonstrates how these benefits can be realized using case studies from existing literature.

KEYWORDS: law, bioethics, methods, ELSI

I. INTRODUCTION

Bioethics is an inherently interdisciplinary field, where questions can be analyzed using a range of perspectives and methodological approaches. Some disciplines are clearly foundational to academic bioethics research because of their role in the field's conceptual origins (eg philosophy) or because they provide easily adaptable tools (eg social science, history).

Law has been widely recognized as a key component of bioethical analysis as well; the standard shorthand for describing the field is ethical, *legal*, and social implications (ELSI) research.[1] Despite that foundational position, law and bioethics are not necessarily an intuitive fit. Law may seem like an isolated and somewhat insular field, focused on identifying or establishing concrete rules and adjudicating specific disputes. But legal analysis can take a range of forms, many of which can complement other disciplinary approaches. Furthermore, law often represents the codification of ethical principles into enforceable rules, which is a necessary step in translating conceptual arguments into practical effects.

Yet, there has been insufficient discussion of how law can best be used as a rigorous analytic framework in bioethics research. Law has long occupied a key role in ELSI analysis, with lawyers and non-lawyers alike pointing to laws, regulations and cases in their analyses. But just like we often appropriately defer to clinicians to explain or discuss a complicated medical topic, specialized legal training is required to fully engage with dense legal sources.

The intent of this paper is to articulate why law is an important tool in bioethics, what methods legal analysis entails, and how it can best be used in the context of bioethics research. Our goal is to outline the various ways that legal research methodologies can help answer ELSI questions, both to better generally define the field but also as a specific resource for lawyers and non-lawyers to better understand how interdisciplinary collaborations with legal scholarship can synergize with other fields of inquiry. Of course, an end goal of interdisciplinary bioethics research is for integrated methodologies that build off each other to combine the strengths of each of the ethical, legal, and social fields. In this paper, however, we focus on the methods specific to the field of law as these are the least well documented in the literature.

II. WHAT IS LEGAL ANALYSIS?

In basic legal reasoning, lawyers first define a particular question related to the topic at hand, such as 'do researchers have a legal obligation to place research results in a

1 Lisa S. Parker et al., *Normative and Conceptual ELSI Research: What It Is, and Why It's Important*, 21 GENETICS IN MED. 505 (2019); *see also* Mark A. Hall & Nancy M.P. King, *Legal Methods*, *in* METHODS IN MEDICAL ETHICS (Jeremy Sugarman & Daniel P. Sulmasy, eds., 2010).

participant's medical record?'[2] Based on the specific contours of this question, legal researchers typically engage in a two-part iterative process of legal analysis: (i) locating relevant sources of law and (ii) interpreting and analyzing the identified text for its application to the question.[3]

The source(s) of the law vary depending on the project. Primary sources of law often include federal and state legislation, federal and state regulations, case law (ie judicial opinions), and executive orders. Legal research can also involve international law or soft governance rules, such as administrative guidance, the policies of Institutional Review Boards (IRBs), or Codes of Ethics. There are different search strategies and research platforms that can be utilized depending on the primary source.[4] Secondary sources, such as legal encyclopedias and treatises, law reviews, interdisciplinary articles, or newspapers, can supplement these primary sources. For example, for the question about research results in the medical record, a potential duty could arise from statutory rules, common law (as established via judicial case law), or professional requirements.[5] Thus, a first step for this project would be to identify relevant sources of legal text and rules related to the issue.

After identifying relevant sources of law, lawyers draw from their legal training to interpret and analyze them. Legal researchers will utilize a range of techniques, such as inductive and deductive reasoning, to extrapolate concrete rules located within the sources.[6] In some cases, a rule is quite clear from the text of a legal source. In other cases, identifying the legal rule or duty—or lack thereof—requires synthesis across several legal sources, such as a handful of judicial opinions or across a range of statutes and regulations. There can be cases where legal sources are in tension with each other, which can raise questions about which to follow given the particulars of the inquiry. There can also be cases, particularly in the context of emerging technologies, where a relevant law or case might not yet exist and conceptualizing what a legal rule will likely require demands analysis by analogy to existing, similar technologies. What's more, identifying when a rule is clear, requires interpretation, or is in tension with other laws can itself require specific legal training.[7]

2 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. Law Med Ethics 827 (2015) [hereinafter Prince, *Automatic Placement*].

3 Terry Hutchinson & Nigel Duncan, *Defining and Describing What We Do: Doctrinal Legal Research*, 17 Deakin L. Rev. 83, 110 (2012).

4 *See, eg* Wendy E. Parmet & Faith Khalik, *Judicial Review of Public Health Powers Since the Start of the COVID-19 Pandemic: Trends and Implications*, 113 Am. J. Pub. Health 280, 280–81 (2023) (explaining the search strategy to identify judicial opinions related to Covid-19); Sarah B. Klieger, et al., *Mapping Medical Marijuana: State Laws Regulating Patients, Product Safety, Supply Chains and Dispensaries*, 112 Addiction 2206, 2207 (2017) (describing methods of identifying state statutes for a 50-state survey).

5 Prince et al., *Automatic Placement*, *supra* note 2.

6 Hutchinson & Duncan, *supra* note 3.

7 The complexity of legal research is apparent in the education requirements for academic legal reference librarians. 'Law librarianship is unique among the academic specialties' as 'no other specialty routinely assumes that the librarian will hold the terminal degree' in the area of service. Law libraries, however, regularly require their reference librarians to have both a master's degree in library and information science and a Juris Doctor. James M. Donovan, *Order Matters: Typology of Dual-Degreed Law Librarians*, 33 Legal Reference Services Q. 1, 1–2 (2014).

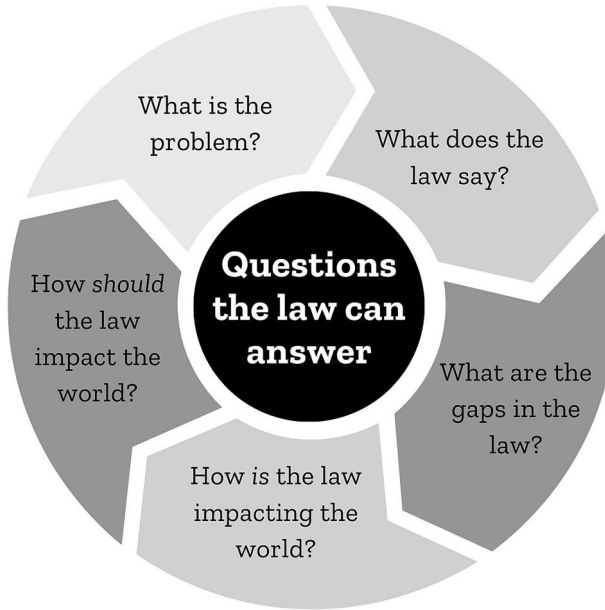

Figure 1. The process of legal analysis in bioethics

Just as in other bioethical disciplines, legal research also employs a division between descriptive and normative elements—between the *is* and the *ought*.[8] Identifying legal sources and interpreting statutes or case law may inform what the law is, but legal analysis can also be leveraged to make claims about what law and policy ought to be (eg if no clear rule exists, or if future developments will require the evolution of an existing rule). This kind of normative analysis is important because courts can, and often do, reference legal literature when novel cases come to their docket. Thus, once the current legal sources and rules are identified, a wide variety of legal questions can be addressed, from identifying gaps in the law to articulating a normative argument about what the law should be.

III. HOW CAN THE LAW ADD VALUE TO BIOETHICS RESEARCH?

Legal analysis can be used to answer a variety of bioethical questions (Fig. 1). These include: (i) What is the problem? (ii) What does the law currently say about the problem? (iii) What are the gaps or uncertainties in the law? (iv) How *is* the law impacting the world? (v) How *should* the law impact the world? These questions iteratively build off one another. Sometimes answering one question can reveal the need to interrogate a new or previous question in light of fresh information.

In this section we highlight examples of research projects that have answered questions within these overarching steps of legal research in bioethics. These examples draw on key ELSI areas, such as reproduction and genetics, but the legal methodologies and approaches are relevant to a wide array of bioethical inquiry. A comprehensive, but by

8 Parker et al., *supra* note 2; Debra J.H. Mathews et al., *A Conceptual Model for the Translation of Bioethics Research and Scholarship*, Hastings Ctr. Rep. 34, 35 (2016).

no means exhaustive list of example legal methods and manuscripts are provided in Table 1.

III.A. What Is the Problem?

As discussed above, usually the first step in legal analysis is to define the scope of the problem. This can be driven by research grant aims or a legal question that has arisen in previous research. Several parameters will impact the scope of analysis. First, one must determine the most relevant type of law for the research question. As noted above, a wide variety of legal sources could be applicable to research questions, such as statutes, case law, regulation, guidance, professional oversight, or treaties.

Second, one must determine what jurisdiction level is the appropriate unit of analysis (ie local, state, federal, or international). For example, an inquiry into how hospitals in Texas are approaching pregnancy care post-*Dobbs* could necessitate an examination of local hospital policies in Texas facilities as well as how they intersect with state law, like malpractice statutes, and federal law, such as the Health Insurance Portability and Accountability Act (HIPAA) and the Emergency Medical Treatment & Labor Act. Whereas a question about global responses to infectious diseases could necessitate exploration of international laws and treaties.

Third, one must determine the relevant time period. Some projects may look at recent case law from the last few years, others may look at statutes passed in the 1800s, while other projects are forward looking and surveil changes to, or impacts of, the law moving forward.

Finally, one should consider the breadth of analysis. Is this a comprehensive analysis that calls for an extensive review of state statutes or does the research question call for a smaller comparative analysis of case law between a handful of jurisdictions? The answers to these questions will impact the scope of legal analysis, the sources utilized to identify and analyze the law, and the resources and expertise needed for the legal team.

III.B. What Does the Law Say?

III.B.1. Research example 1: the state of the law

Perhaps the most basic questions that lawyers can answer for the bioethics community are: what is the current state of the law on a topic and how is policy changing over time? While these are basic questions, they are by no means simple. For example, relevant to this question is what jurisdiction (eg international, federal, state) to assess, what source of law (eg statute, regulation, case law, guidance), whether there are conflicting rules in different jurisdictions, and how much to evaluate other impacts on the law (eg choice of law, private rights of action).

Fifty-state surveys are one version of this kind of research, sometimes called legal mapping or policy surveillance. They involve systematic identification and analysis of relevant state laws.[9] For example, in *The problems with patchwork: State approaches to regulating insurer use of genetic information,* the research team of lawyers and law students developed a database of state laws regulating life, long-term care, and disability insurers' use of genetic information.[10] This survey was completed as part of an NIH-funded

9 Scott Burris et al., *Policy Surveillance: A Vital Public Health Practice Comes of Age*, 41 J. Health Pol., Pol'y & L. 1151 (2016).

10 Anderson, Lewis & Prince, *supra* note 9.

Table 1. Example legal analysis and methods

Example methodologies include:	Example manuscripts include:	Summaries:
What does the law say?		
50-State Survey	Anderson et al. (2021); Fox (2022); Ram (2021); Wolf et al. (2019)[78]	50-state survey of laws governing the use of genetic information in life, long-term care, and disability insurance; 50-state survey of 'fertility fraud' legislation; 50-state survey of state policies on law enforcement access to newborn screening samples and related data; survey of state and federal laws protecting participants in genetic research.
Case Law/Common Law Review	Hodge et al. (2024); Mello & Parmet (2023); Suter (2016); Ziaks et al. (2025)[79]	Summarizing the public health implications of cases decided in the Supreme Court's 2023–2024 term; considering how a Supreme Court decision on religious accommodations will affect employers' abilities to enforce vaccine mandates; describing and analyzing judicial interpretations of 'genetic information' in GINA's first decade; assessing the evoluation of labeling pathways for generic drugs
Content analysis	Wolf et al. (2024)[80]	Conducting a content analysis of consent forms and protocols for information about paying research participants
Cross sectional study	Memedovich et al. (2025)[81]	Constructing predictive models to determine the factors that affect generic competition in drug-manufacturing
International comparative analysis	Mohapatra (2012); Prince (2019)[82]	Exploring whether reproductive justice is being achieved in the surrogacy market in India, Ukraine and the United States; comparing regulations of life, disability, and critical illness insurers in the United Kingdom, Canda, and Australia regarding their use of genetic test results for underwriting.
Literature review	Levinson et al. (2020)[83]	Analyzing the legal and ethical duties related to disclosure after discovering a hot spot of suicidality in an anonymous student health survey

(Continued)

Table 1. Continued.

Example methodologies include:	Example manuscripts include:	Summaries:
Multi-Source Review (ie professional guidance, statute, case law)	Prince et al. (2015); Sanner et al. (2021)[84]	Analyzing the legal and ethical duties related to automatically putting genomic research results in personal medical records; discussing the challenges of intrastate policy surveillance in Indiana
What are the gaps in the law?		
Ethical analysis	Bonham et al. (2016); Spector-Bagdady (2025); Suter (2016)[85]	Arguing that precision medicine might be able to alleviate imperfect race-based assumptions about genetic ancestry and associated genotype increasing equitable access to tailored drug regimens; arguing that communities should draft integrity standards to govern the use of generative AI in research prospectively, instead of waiting for harm to occur; evaluating the harms and benefits of *in vitro* gametogenesis using a relational autonomy framework
Regulatory analysis	Guerrini et al. (2020); Price & Cohen (2019)[86]	Describing the federal regulatory landscape governing third party genetic interpretation services and concluding that existing authorities could adequately protect against risks; discussing the health privacy implications of big data, considering applicable regulations.
Legal analysis	Beskow & Wolf (2022); Fox (2023)[87]	Considering how the patchwork of state laws governing research could impact the development of precision medicine and suggesting reforms, including a choice-of-law framework; examining the legal asymmetry in medical conscience laws that protect clinician who claims conscience to refuse standard-of-care services, but fail to protect providers who conscientiously provide standard care when a state or institution prohibits its delivery.

(Continued)

Table 1. Continued.

Example methodologies include:	Example manuscripts include:	Summaries:
How *is* the law impacting the world?		
Policy Delphi	Robinson et al. (2023)[88]	Using a modified policy Delphi with expert stakeholders to evaluate and rank policy options regarding data sharing of gene variants and relevant clinical data for cancer genomics research.
Interviews	Arias et al (2024); Guerrini et al. (2017); Trinidad et al. (2023)[89]	Describing benefits of and challenges with sharing data and returning results in frontotemporal lobar degeneration research involving genetic data; describing the impact of U.S. Supreme Court patent eligibility jurisprudence on decisions to protect genetic innovations as patents or trade secrets; describing experiences with conducting genetic research with various databases, including legal burdens on access.
Database research	Druedahl et al (2021)[90]	Evaluating WHO database of Covid-19 vaccine candidates to assess prevalence and mode of research collaboration for pandemic preparedness and response
Surveys	Tobia et al. (2021)[91]	Using an online survey to assess potential jurors' liability judgments relating to physician acceptance or rejection of artificial intelligence treatment recommendations.
How *should* the law be impacting the world?		
Focus groups	Spector-Bagdady et al. (2024)[92]	Reporting a mixed methods analysis with a patient survey and focus groups to asses response to a new consent form and marketing materials disclosing research use of data and specimens
Surveys	Guerrini et al. (2025); Jaffe et al. (2024), Mello et al. (2018)[93]	Describing research participants' privacy perspectives related to neuroscience data and explaining implications for adoption of anti-discrimination legislation; describing genetic researchers' interest in research with diverse ancestral groups and exploring ways to increase access to ancestrally diverse databases; describing clinical trial participants' perceptions of data sharing risks, including concerns about use for marketing.

(Continued)

Table 1. Continued.

Example methodologies include:	Example manuscripts include:	Summaries:
Conceptual Analysis	Roesner et al. (2022); Suter (2023)[94]	Evaluating the justifications for laws that ban abortions based on genetic diseases or disability and concluding that, despite rhetoric aligning such laws with the disability rights movement, the laws are more closely tied to anti-abortion goals; demonstrating that states that ban abortions based on race, sex, or disability allegedly to prevent 'eugenics' and discrimination do not make similar efforts in other areas of law, suggesting the bans are instead motivated by anti-abortion sentiment and showing that they actually harm the very groups that have been targets of eugenics and discrimination

*This table is intended to provide a handful of example methodologies and example articles for each legal question. It is by no means an exhaustive list of either methods or publications. [78]Jarrod O. Anderson, Anna C.F. Lewis & Anya E.R. Prince, *The Problems with Patchwork: State Approaches to Regulating Insurer Use of Genetic Information*, 22 DePaul J. Health Care L. 1 (2021); Dov Fox, *'Fertility Fraud' Legislation—A Turning Point in Informed Consent?*, 387 New Eng. J. Med. 770 (2022) [hereinafter Fox, *Fertility Fraud*]; Natalie Ram, *America's Hidden National DNA Database*, 100 Tex. L. Rev. 1253 (2021) [hereinafter Ram, *DNA Database*]; Leslie E. Wolf et al., *The Web of Legal Protections for Participants in Genomic Research*, 29 Health Matrix Cleveland 1 (2019) [hereinafter Wolf et al., *Legal Protections*]. [79]James G. Hodge et al., *Supreme Court Impacts in Public Health Law: 2023–2024*, 52 J. L. Med. Ethics 484 (2024); Michelle Mello & Wendy E. Parmet, *Accommodating Religious Objections to Vaccination Mandates-Implications of* Groff v DeJoy *for Health Care Employers*, 4 JAMA Health Forum e233672 (2023); Sonia M. Suter, *GINA at Ten Years, The Battle over 'Genetic Information' Continues in the Courts*, 5 J.L. & Biosciences 495 (2019) [hereinafter Suter, *GINA at Ten*]; Therese J. Ziaks et al., *Frequency of First Generic Drugs Approved Through 'Skinny Labeling,' 2021 to 2023*, 31 J. Manag. Care Spec. Pharm. 343 (2025). [80]Leslie E. Wolf, Samantha Kench, & Christy J.W. Ledford, *A Taxing Problem: The Impacts of Research Payment Practices on Participants and Inclusive Research*, 19 PLoS One e0303112 (2024). [81]Ally Memedovich et al., *Predicting Patent Challenges for Small-Molecule Drugs: A Cross-Sectional Study*, 22 PLoS Med. e1004540 (2025). [82]Seema Mohapatra., *Achieving Reproductive Justice in the International Surrogacy Market*, 21 Annals Health L. 191 (2012); Anya E.R. Prince, *Comparative Perspectives: Regulating Insurer Use of Genetic Information*, 27 J. Human Genetics 340 (2019). [83]Arnold H. Levinson et al., *Duties When an Anonymous Student Health Survey Finds a Hot Spot of Suicidality*, 20 Am. J. Bioethics 50 (2020). [84]Prince et al., *Automatic Placement*, *supra* note 2; Lindsey Sanner et al., *The Challenges of Conducting Intrastate Policy Surveillance: A Methods Note on County and City Laws in Indiana*, 111 Am. J. Public Health 1095 (2021). [85]Vence L. Bonham, Shawneequa L. Callier, & Charmaine D. Royal, *Will Precision Medicine Move Us beyond Race?*, 374 N. Engl. J. Med. 2003 (2016); Kayte Spector-Bagdady, *The Need for Prospective Integrity Standards for the Use of Generative AI in Research*, J. L. Med. Ethics 1 (2025); Sonia M. Suter, *In Vitro Gametogenesis: Just Another Way to Have a Baby?*, 3(1) J.L. & Biosciences 87 (2016) [hereinafter *In Vitro*]. [86]Christi J. Guerrini, Jennifer K Wagner, Sarah C Nelson, Gail H Javitt, & Amy L McGuire, *Who's on Third? Regulation of Third-Party Genetic Interpretation Services*, 22 Genetics Med. 4 (2020); W. Nicholson Price & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, 25 Nat. Med. 2019. [87]Laura M. Beskow & Leslie E. Wolf, *'Choice of Law' in Precision Medicine Research*, 109 Am. J. Human Genet. 1347 (2022); Dov Fox, Medical Disobedience, 136 Harv. L. Rev. 1030 (2023). [88]Jill O. Robinson et al., *Policy Options to Facilitate Cancer Genomic Variant Data Sharing: Outcomes of a Modified Policy Delphi*, 10 *J. Law & Biosciences 1* (2023). [89]Jalayne J. Arias et al., *Data Stewardship in FTLD Research: Investigator and Research Participant Views*, 20 Alzheimer's Dement. 2886 (2024); Christi J Guerrini et al., *Constraints on Gene Patent Protection Fuel Secrecy Concerns: A Qualitative Study*, 4 *J. Law & Biosciences* 542 (2017); M. Grace Trinidad et al., *'Extremely Slow and Capricious': A Qualitative Exploration of Genetic Researcher Priorities in Selecting Shared Data Resources*, 25 Genet Med. 115 (2023). [90]Louise C. Druedahl, *Collaboration in Times of Crisis: A Study on COVID-19 Vaccine R&D Partnerships*, 39 Vaccine 6291 (2021). [91]Kevin Tobia, Aileen Nielson, & Alexander Stremitzer, *When Does Physician Use of AI Increase Liability?*, 62 J. Nucl. Med. 17 (2021); . [92]Kayte Spector-Bagdady et al., *Lessons for a Learning Health System: Effectively Communicating to Patients about Research with their Health Information and Biospecimens*, 9 Learn Health Syst. e10450 (2024). [93]Kaitlyn Jaffe et al., *Genetic Researchers' Use of and Interest in Research With Diverse Ancestral Groups*, 7 JAMA Netw Open e246805 (2024); Michelle M. Mello, Van Lieou, & Steven N. Goodman, *Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing*, 378 N. Engl. J. Med. 2202 (2018). [94]Nina Roesner et al., *Reason-Based Abortion Bans, Disability Rights, and the Future of Prenatal Genetic Testing*, 49 AM. J. L. & Med. 187, 199 (2022); Sonia M. Suter, *Why Reason-Based Abortion Bans Are Not a Remedy Against Eugenics: An Empirical Study*, 10 J Law Biosci. 1 (2023)

project exploring genetic discrimination in non-health insurance.[11] The first step of the process was to define the scope. Non-health insurance in the US is predominately regulated at the state level. Therefore, the project focused on state statutes in this area. As discussed above, other projects may call for an analysis of international or federal law. Based on a literature review of previous legal mapping on the topic, the researchers developed search terms to identify relevant statutes and a questionnaire to assess each statute, similar to a codebook in qualitative research. A team of research assistants then double coded all identified laws. As a final check, a licensed attorney read each identified statute and compared the research assistant coding to previous mapping efforts, focusing on areas of disagreement in interpretation. Any errors were recoded.

Identifying the legal landscape allows for in-depth analysis of legal trends, dissemination of laws to key stakeholders, and identification of gaps in the law. For example, the genetic discrimination in insurance project culminated in a publication highlighting trends in state legislation,[12] continued tracking of new legislation meeting the search criteria[13], and a public-facing map illustrating the current state of the law.[14] Other examples of legal mapping of state surveys in bioethics include a survey of state laws regarding fertility fraud,[15] law enforcement access to and use of genetic material,[16] and genetic research protections.[17]

As mentioned, a 50-state survey is not appropriate for all legal mapping of the current state of the law. For example, in an article focused on citizen science applications of genome editing technologies, the authors examined the landscape of federal laws that could regulate this novel use of biomedical technologies.[18] Other projects focus more on the courts and case law.[19]

III.B.2. Research example 2: interpreting the meaning of a law

Sometimes, identifying the relevant cases or statutory sections is relatively straightforward, while determining what that law requires is the more difficult task. In interpreting statutory text, for instance, judges may rely on a veritable stable full of canons of interpretation.[20] Predicting how a particular court is likely to interpret past precedent or statutory language can be fraught, and it is not even clear whether such prediction

11 Grant No R00HG008819 (Anya Prince, PI), Nat'l Insts. Of Health (2015–2020) (Use of Genetic Information by Life, Long-term Care, and Disability Insurers).

12 Anderson, Lewis & Prince, *supra* note 9.

13 Anya E.R. Prince, *The Genetic Information Privacy Act: Drawbacks and Limitations*, 330 JAMA 2049 (2023).

14 *Genetic Privacy in US: Insurance and Law Enforcement Use*, (forthcoming website).

15 Fox, *Fertility Fraud, supra* note 9.

16 Natalie Ram, *Fortuity and Forensic Familial Identification*, 63 Stan. L. Rev. 751 (2011); Ram, *DNA Database*, *supra* note 9.

17 Wolf et al., *Legal Protections, supra* note 9.

18 Christi J. Guerrini, G. Evan Spencer & Patricia J. Zettler, *DIY CRISPR*, 97 N.C. L. Rev. 971,399 (2019); *see also* Naomi Cahn & Sonia M. Suter, *The Art of Regulating ART*, 96 Chi.-Kent L. Rev. 29 (2022).

19 Edward Ramos, Shawneequa L. Callier, Peter B. Swann, & Hosea H. Harvey, *Genomic Test Results and the Courtroom: The Roles of Experts and Expert Testimony*, 44 J. L. Med. & Ethics 205 (2016).

20 *See, eg* Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons*, 65 Stan. L. Rev. 901 (2013) (reviewing many canons of statutory interpretation and comparing them with actual congressional practice); Jacob Scott, *Codified Canons and the Common Law of Interpretation*, 98 Geo. L.J. 341 (2010) (reviewing state statutory codifications of rules for interpreting the legislature's handiwork and comparing them with common law canons developed by judges).

is properly the province of the academic or even the lower court judge.[21] Sometimes the nature of a statutory commitment can only be made clear from a perspective that straddles multiple fields of law.

Consider, for instance, the Certificate of Confidentiality statute.[22] Certificates of Confidentiality can be issued to both federally funded and non-federally funded researchers, and they protect the privacy of research participants. More specifically, a Certificate obligates its recipient researcher not to disclose sensitive research data 'in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.'[23] Congress originally enacted the statute creating Certificates of Confidentiality in the 1970s as part of the war on drugs, and Congress has returned to the Certificate statute on multiple occasions over intervening decades, each time broadening or strengthening the Certificate's reach. All the while, however, many researchers have not known about Certificates, while IRBs and general counsel at research institutions have expressed uncertainty about how a Certificate functions and how it can be enforced when an outside demand for access to protected data materializes.[24]

Recent exploration of the Certificate statute, however, has shed light on *what* a Certificate of Confidentiality is and how it should function. Drawing on the fields of evidence law and criminal procedure, as well as research ethics and law, researchers revealed that the Certificate statute is not doing something odd or strange, but rather something relatively straightforward and remarkable: creating a statutory privilege. A significant body of case law has developed on the topic of federal statutory privileges, how to recognize one, and how to construe it. Through this legal lens, it becomes clear that the Certificate statute codifies a statutory privilege, and indeed a strong one.[25] Situating the Certificate statute under privilege law allows for cogent analysis of many questions that have plagued researchers and their institutions: how Certificates operate, whether and under what circumstances Certificates can be constitutionally applied,[26] and how courts should analyze disputes over data protected by a Certificate.[27] Moreover, privilege law and criminal procedure doctrines inform how consent to disclosures from research participants may—and may not—be obtained.[28]

Certificates of Confidentiality have thus long been known to the research institutions charged with approving and overseeing research, but the meaning, weight, and protections afforded by Certificates remained obscured. Legal analysis bridging fields within the law was necessary to shed light on Certificates. Similar analysis has been

21 Richard M. Re, *Narrowing Supreme Court Precedent from Below*, 104 Geo. L.J. 921 (2016).

22 *See*, eg Natalie Ram, *Privileging Genetic Privacy*, 74 Emory L.J. (forthcoming 2025) [hereinafter Ram, *Privileging Genetic Privacy*]; Natalie Ram, Jorge L. Contreras, Laura M. Beskow & Leslie E. Wolf, *Constitutional Confidentiality*, 80 Wash. & Lee L. Rev. 1349 (2023) [hereinafter Ram et al., *Constitutional Confidentiality*]; Natalie Ram & Leslie E. Wolf, *Act on a Mandate to Protect Research Subjects' Privacy*, 386 Science 1096 (2024); Leslie E. Wolf, Natalie Ram & Elizabeth J. Letourneau, *Certificates of Confidentiality and Mandatory Reporting*, 178 JAMA Peds. 639 (2024).

23 42 U.S.C. § 241(d)(1)(D).

24 Ram et al., *Constitutional Confidentiality*, *supra* note 38, at 1367–68.

25 *See* Ram et al., *Constitutional Confidentiality*, *supra* note 38, at 1368–74; Ram, *Privileging Genetic Privacy*, *supra* note 38.

26 Ram et al., *Constitutional Confidentiality*, *supra* note 38 at 1375–1434.

27 Ram, *Privileging Genetic Privacy*, *supra* note 38.

28 *Id.*

done with respect to the impact of new technologies in medical care to help clinicians understand where the law is clear and where uncertainties remain.

III.C. How Can the Law Be Improved?

Legal, ethical, and regulatory analysis can also point to ways that the law can be improved (Table 1). Particularly in the biosciences, rapidly developing and emerging technologies can create gaps in the law where none may have previously existed.

III.C.1 Research example 3: Gaps in the law

The law may fail to keep pace or be unable to cope with innovations that disrupt entrenched legal values or doctrines.[29] Some examples include neuroscience,[30] nanotechnology,[31] artificial intelligence[32] , and 'big data.'[33] Emerging technologies and evolving research methodologies have the potential to give rise to legal gaps or puzzles, making it useful to ask whether these biomedical developments outstrip the systems that society has established to govern them.[34] For example, do these advances generate uncertainty in the application of existing rules to new practices? Do advances lead those rules to be over- or under-inclusive? Do scientific advances obviate a premise that had previously justified those rules? Do emerging scientific findings and approaches demand new specially-tailored governance approaches?[35]

The cutting edge of genetic science and reproductive technology is a case in point, in matters from artificial wombs to gene editing to in vitro gametogenesis.[36] Interventions like in vitro fertilization and embryo screening have emerged as the medicine of miracles, filling embryo cribs and freeing families from devastating disease.[37] These advances are regulated only lightly, however, inviting distinctive forms of reproductive injury.[38]

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29 Laurence H. Tribe, Channeling Technology Through Law (1972); Lyria Bennett Moses, *The Legal Landscape Following Technological Change: Paths to Adaptation*, 27 Bull. Sci., Tech. & Soc'y 408 (2007); Gaia Bernstein, *Accommodating Technological Innovation: Identity, Genetic Testing, and the Internet*, 57 Vand. L. Rev. 965 (2004); David Friedman, *Does Technology Require New Law?*, 25 Harv. J.L. & Pub. Pol'y 71 (2001).

30 Dov Fox, *The Right to Silence Protects Mental Control*, 42 Akron L. Rev. 763 (2009), *reprinted in* Law and Neuroscience (Michael Freeman ed., 2010); Owen Jones et al., Law and Neuroscience (2014).

31 Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. Cal. Interdisc. L.J. 593 (1994).

32 Hin-Yan Liu et al., *Artificial Intelligence and Legal Disruption: A New Model for Analysis*, 12 Law, Innovation & Tech. 205 (2020).

33 Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 Yale L.J. 710 (2019); Spector-Bagdady, *supra* note 15; Shawneequa Callier & Anya E.R. Prince, *The Legal Uncertainties of Sociogenomic Polygenic Scores*, 38 Harvard J. L. & Tech. 553 (2024).

34 John H. Pearson, *Regulation in the Face of Technological Advance: Who Makes These Calls Anyway?*, 13 Notre Dame J.L. Ethics & Pub. Pol'y, 1 (1999).

35 Lyria Bennett Moses, *Recurring Dilemmas: The Law's Race to Keep Up with Technological Change*; 2007 U. Ill. J.L. Tech. & Pol'y 239 (2007).

36 Sonia M. Suter, *In Vitro, supra* note 15; Cahn & Suter, *supra* note 34; Nina Roesner, S. McGrew S, Chloe Connor & Ben E. Berkman, *Artificial Womb Technology: Emerging Legal and Bioethical Debates in Ectogestation,* Yale J. Health Pol'y, L. & Ethics (forthcoming).

37 Dov Fox, *Reproductive Negligence*, 117 Colum. L. Rev. 149 (2017).

38 Dov Fox, *Making Things Right When Reproductive Medicine Goes Wrong: Reply to Robert Rabin, Carol Sanger, and Gregory Keating*, 118 Colum. L. Rev. F. 94, 116–17 (2018), https://columbialawreview.org/content/making-things-right-when-reproductive-medicine-goes-wrongreply-to-robert-rabin-carol-sanger-a

The injuries borne of these loosely-regulated interventions fall through the cracks of legal systems available to recognize and remedy them—when reproductive negligence leaves victims without the baby they set out to have; leaves them with the very child they'd set out to avoid having; or with a child who's born less healthy or genetically related or otherwise distinct than they had reason to expect.[39] Judges have resisted legal redress for such reproductive losses under existing theories of contract, property, and tort doctrines like fraud and false advertising, negligence and products liability, informed consent and medical malpractice hybrids like wrongful birth, wrongful life, and wrongful pregnancy.[40] Some courts insist that even unplanned babies are blessings, and shrug that infertile couples weren't assured offspring anyway. Others are resigned that these tragedies are just part of modern life that lie beyond the power of any judicial system to do anything about. The result is a society that lets badly behaving specialists off the hook and leaves broken victims to pick up the pieces.

Identifying gaps in the law is a beneficial research endeavor in and of itself. Yet legal research can also help identify ways to solve gaps in the law. For example, ELSI scholarship has sought to close these gaps by introducing new rights to address reproductive wrongs like mismanaged pregnancies or mishandled embryos.[41] Some impose unwanted procreation—any baby cases.[42] Others deprive parenthood from those who long for it—no baby cases.[43] Others still confound plans not just for any child, but for one born with or without particular traits—different baby cases.[44] This ELSI work has proposed new causes of legal action that correspond to each distinct form of reproductive harm: procreation imposed, procreation deprived, and procreation confounded.[45] And it's developed a detailed structure for awarding damages for successful courthouse claims against misconduct that results in these respective forms of injury.[46] This framework, part subjective and part objective, guides jury verdicts with instructions tailored to each and illuminates the outsized role of racial and class biases in existing determinations about 'worthy' kids and 'deserving' parents.[47]

Another example of legal scholarship that shed light on gaps in the law concerned the familial nature of genetic information.[48] Various forms of law recognize genetic data as sensitive and private, including the federal Genetic Information Nondiscrimination Act (GINA) and state-level DNA property statutes. But existing legal frameworks touching on genetics largely fail to acknowledge, much less account for, the shared

nd-gregory-keating/ [https://perma.cc/MJB5-P2BW]; Dov Fox, *Redressing Future Intangible Losses*, 69 DePaul L. Rev. 419 (2020); Dov Fox, *Family Planning and Its Limits*, 23 J. Contemp. Legal Issues 87, 93 (2021).

39 Dov Fox, *Birth Rights and Wrongs: A Reply to Critics*, 100 B.U. L. Rev. Online 160 (2020).

40 Dov Fox, Birth Rights and Wrongs: How Medicine and Technology Are Remaking Reproduction and the Law (2019).

41 *Id.* at 6–8.

42 *Id.* at 113–26.

43 *Id.* at 99–112.

44 *Id.* at 127–40.

45 *Id.* at 60–71.

46 *Id.* at 87–95.

47 Dov Fox & Jill Wieber Lens, *Valuing Reproductive Loss*, 112 Geo. L.J. 61 (2023).

48 Natalie Ram, *DNA By The Entirety*, 115 Colum. L. Rev. 873 (2015) (tenancy by the entirety framework reveals how officials might approach the issue of accounting for interests that lie in shared identifiable genetic information).

nature of genetic information. We all share genetic information that can be used to learn about and identify us with a broad swath of genetic relatives, and that sharing is both involuntarily thrust upon us and immutable. Exposing existing law's failure to account for the interests that lie in shared identifiable genetic information is itself productive, as it exposes how that law only reaches a portion of the relevant interests that can be affected by the sharing or taking of biospecimens and genetic data from a single individual. This inquiry can also tee up further lines of inquiry, both descriptive and normative. As to the descriptive, questions might include whether other bodies of law have grappled with similarly difficult forms of overlapping, interdependent, involuntary, and immutable interests; and how attending to these interests might affect the legal status quo. As to the normative, scholarship might question whether legally salient interests ought to attach to information that is learned from analyzing person A's cells, when that information is used to learn about or identify person B.

The myriad of articles written about gaps in the law, especially related to emerging technologies in bioethics highlights this important legal analysis.[49]

III.D. How Is the Law Impacting the World?

III.D.1. Research example 4: updates to the law

Another function of legal scholarship written for scientific and medical audiences is to educate researchers, physicians, bioethicists, and other health care workers about recent changes to the law that could impact them.[50] This variety of scholarship often summarizes the text and potential implications of new or updated sources of law, including state or federal legislation, state or federal regulations, state or federal executive orders and declarations, and judicial opinions. The goal is to explain sometimes highly complex legal ideas and principles to non-lawyers in an accessible, easy-to-understand manner, to outline the context and significance of these shifts in the law, and to briefly forecast how those changes might affect the article's audience or to suggest actions that the article's audience should take because of the new laws or regulations.

We are living in an era characterized by rapid and significant changes in laws and the systems that interpret and execute them. Thus, ensuring that stakeholders are aware of the current state of the law is increasingly important, yet also increasingly difficult. Explaining updates to the law inevitably also involves the first category of scholarship:

49 *See*, eg Seppe Segers & Elizabeth Chloe Romanis, *Ethical, Translational, and Legal Issues Surrounding the Novel Adoption of Ectogestative Technologies*, 15 Risk Mgmt. & Healthcare Pol'y 2207 (2022); Daniel Susser et al., *Synthetic Health Data: Real Ethical Promise and Peril*, 54 Hastings Ctr. Rep. 8 (2024); Dov Fox, *The Second Generation of Racial Profiling*, 38 Am. J. Crim. L. 49 (2010); Nat'l Acads. of Sci., Eng'g & Med. et al., Exploring the Legal Implications of Emerging Neurotechnologies: Proceedings of a Workshop (Nat'l Acads. Press, 2018); Karen Davis et al., *Brain Imaging Tests for Chronic Pain: Medical, Legal and Ethical Issues and Recommendations*, 13 Nature Revs. 624 (2017); Patricia Zettler et al., *Regulating Genetic Biohacking*, 365 Sci. Mag. 34 (2019); Mais Qandeel, *Facial Recognition Technology: Regulations, Rights and the Rule of Law*, 7 Frontiers in Big Data 1 (2024); Alexandra Foulkes et al., *Legal and Ethical Implications of CRISPR Applications in Psychiatry*, 97 N.C. L. Rev. 1359 (2019); Eli Adashi, Katsuhido Hayashi, & I. Glenn Cohen, *Ethical and Legal Challenges in Assisted Same-Sex Conception through In Vitro Gametogenesis*, 30 Nature Med. 322, 322–323 (2024); Sonia Suter, *Legal Challenges in Reproductive Genetics*, 115 Fertility & Sterility 282 (2021); Jessica L. Roberts & Sonia M. Suter, *Damned If You Do or Damned If You Don't: The Medical Malpractice Implications of Consumer-Generated Polygenic Scores*, 38 Harv. J. L. & Tech. 417 (2024).

50 Mello & Parmet, *supra* note 10; Hodge et al., *supra* note 10.

interpreting the meaning of the law. Authors writing in this area must explain the status quo before they can provide information regarding what has changed. Even in the case of familiar areas of law, like medical malpractice or the Common Rule, papers explaining legal updates must offer an account of the baseline for readers to fully comprehend the implications of changes. The key distinction between articles that discuss legal meaning and articles that discuss change is temporal. The first category may explain a well-settled, yet perhaps not well-known, body of law. The second category focuses on recent changes—the impacts of which remain unclear. This category of legal work serves not only as a legal primer, but also as a news briefing, so that people in the field can gain a sense of the changes that are to come. The goal of these updates can range from simply providing information that could affect research or medical practice, to flagging emerging issues, to assuaging concerns related to misinformation.

Consider *Antidiscrimination Law Meets Artificial Intelligence*, which outlines changes to the federal regulations governing Section 1557 of the Affordable Care Act that pertain to medical AI.[51] It begins by briefly explaining the scope and applicability of Section 1557 and how the updates clarify that Section 1557's prohibition on discrimination includes the use of patient decision support tools, such as medical AI. The new rule requires covered entities to review whether their decision support tools use protected traits like race, sex, age, or disability, as inputs and, if they do, to make reasonable efforts to mitigate any discriminatory impacts. The article also outlines the process that the Department of Health and Human Services will use for enforcement. Importantly, the article addresses common misconceptions regarding the rule's potential impact. The new rule does not forbid the use of protected traits as inputs outright. In fact, it expressly allows their use when it is clinically indicated or conforms with best practices. As a result, the article assures health care providers and other covered entities that they can continue using decision support tools, like algorithms and AI, even if they employ protected traits, so long as they have valid reasons to do so.

III.D.2. Research example 5: Elicit experiences with and perspectives on the law

Legal expertise is also a critical input in the design and analysis of research to elicit public and expert perspectives on regulation or the absence of regulation in a particular area. Public and expert opinion can inform understanding of how extant law (or lack thereof) is functioning in the real world, which can point towards potential areas of improvement. For these studies, identification and interpretation of relevant laws and policies are necessary to frame the research questions, develop study instruments and other materials, analyze the data, and determine implications for policymakers.

An example of research involving the public is a general population survey conducted by two legal scholars to understand lay perspectives on 21 law enforcement activities, nine of which related to DNA collection or access.[52] The research was grounded in a comprehensive survey of relevant federal laws, regulations, and judicial opinions; survey questions were framed to reflect Fourth Amendment jurisprudence. The study results informed the team's conclusions that both police access to non-

51 Michelle M. Mello & Jessica L. Roberts, *Antidiscrimination Law Meets Artificial Intelligence—New Requirements for Health Care Organizations and Insurers*, JAMA Health F. Aug. 2024.

52 James W. Hazel & Christopher Slobogin, *'A World of Difference'? Law Enforcement, Genetic Data, and the Fourth Amendment*, 70 Duke L. J. 705 (2021).

governmental genetic databases and police use of covert methods to collect DNA in the hope of matching crime scene DNA require judicial authorization, although not necessarily a traditional warrant.

ELSI research is also frequently conducted with key informants or other experts who can provide nuanced perspectives and opinions about a policy area based on their experiences navigating regulations or conducting activities in the absence of regulatory guardrails. Such data were collected, for example, in an interview study conducted with 24 individuals knowledgeable about investigative genetic genealogy (IGG).[53] A second example, also concerning IGG, is a policy Delphi[54,55] conducted with over 30 experts in law, bioethics, law enforcement, genetic genealogy, and database operations.[56] The lawyer-led research team guided the expert research participants in a series of virtual engagement sessions and asynchronous surveys to identify the most pressing problems with IGG and to generate and evaluate a range of policy solutions that included making specific changes to federal and state laws. To elicit and interpret experts' relevant experiences with and opinions on relevant policies, as well as where policies are needed, it was necessary for the team to first analyze IGG laws, genetic privacy laws, and criminal laws that impact IGG practice. This initial research was supplemented by additional legal research carried out in response to expert statements that were provided and policy changes that occurred throughout the course of the year-long study. The study outcome is a set of informed recommendations to guide policymakers interested in regulating IGG.

Combining legal expertise in survey and other empirical methods design has been widely utilized in biomedical, legal research, such as a survey of insurance regulators regarding practices surrounding genetic information[57] or about patient understanding and response to different types of medical informed consent disclosures[58] or physicians' perspectives of the use of race in medication prescribing.[59]

III.E. How Should the Law Be Impacting the World?

III.E.1. Research example 6: normative analysis and legal theory

Legal scholarship can also act as a bridge between legal theory and normative analysis. Though it is not always the case that 'legal' is synonymous with 'ethical,' law often serves as a codification of social value and norms. Law can be an important mechanism for translating ethical debates and difficult policy tradeoffs into consistent, enforceable rules. Unfortunately, the relationship between law and norms is not always clearly explicated; legal scholarship can be necessary to analyze the connection. This can

53 Christi J. Guerrini et al., *IGG in the Trenches: Results of an In-Depth Interview Study on the Practice, Politics, and Future of Investigative Genetic Genealogy*, 356 Forensic Sci Int'l. 1 (2024).

54 Robert C. de Loe, *Exploring Complex Policy Questions Using the Policy Delphi: A Multi-Round, Interactive Survey Method*, 15 Applied Geography 53 (1995).

55 Murray Turoff, *The Design of a Policy Delphi*, 2 Tech. Forecast Soc Change. 149 (1970).

56 Christi J. Guerrini et al., *Investigative Genetic Genealogy Practices Warranting Policy Attention: Results of a Modified Policy Delphi*, 21 PLOS Genetics 1 (2025).

57 Dexter R. Golinghorst & Anya E.R. Prince, *A Survey of U.S. State Insurance Commissioners Concerning Genetic Testing and Life Insurance: Redux at 27*, 29 J. Genetic Counseling 928 (2020).

58 Spector-Bagdady et al., *supra* note 22.

59 Shawneequa L. Callier et al. *Cardiologists' Perspectives on BiDil and the Use of Race in Drug Prescribing*, 9 J. Racial & Ethnic Health Disparities 2146 (2022).

involve exploring the normative assumptions and principles inherent in the way a given law has been structured. It can also involve drawing on normative theory as a source of persuasive arguments to help resolve open legal questions.

As an example of this latter function, take the ethically complicated emergence of new reproductive technologies. Specifically, recent advances in prenatal genetic testing have made testing for congenital disorders and future health risks more accessible, with emerging technologies auguring a further broadening of available testing options (eg non-invasive prenatal whole genome sequencing). While access to more information about a fetus certainly allows parents to better prepare for the birth of a child with a disability, it also can present families with a difficult choice about whether to terminate a pregnancy to avoid having to raise a child with a disability. Disability rights advocates have raised concerns about this kind of selective termination on the basis of genetic testing, arguing that doing so sends a negative message about the value of a person already living with a disability.

There has been a vigorous academic debate about these expressivist concerns, but an interesting tension emerged when advocates, lawmakers and judges began using similar arguments to advance anti-abortion policies. For example, in one notable Supreme Court concurrence, Justice Thomas argued that state restrictions on the allowable reasons for terminating a pregnancy (ie reason-based abortion bans) were permissible because they mitigated the eugenic and expressivist impacts of legal abortions.[60] On its face, using disability rights arguments to support anti-abortion policy could plausibly have some persuasive power. But an academic analysis of how these kinds of normative arguments were being used demonstrated the inherent weakness of appealing to disability rights arguments to support anti-abortion policies. Rather, the use of disability rights normative arguments actually served to 'pit reproductive rights against disability rights . . . inhibit[ing] coalition-building that could achieve meaningful policy change and make the world a more inclusive, accessible place for those with disabilities.'[61] Similarly, a related project argued that reason-based abortion bans are not the remedy against eugenics that they claim to be. States with such bans have not implemented policies to counteract eugenics more broadly. Instead, the 'apparent motivation [for such laws] is to commandeer concerns about eugenics to restrict reproductive rights,' which ultimately harms the very groups negatively 'impacted by the eugenics movements—minorities, women, people with disabilities, the LGBTQ+ community, and immigrants.'[62]

Though genetics and reproductive technologies are often high-profile topics subject to legal and ELSI analysis, the legal bioethics literature is rife with examples of normative and conceptual analysis.[63] For example, during COVID, many pressing questions arose that required an exploration of how the law should be working, such as normative questions about how the law should treat prisoners who were at enhanced risk of infection because of higher frequency of pre-existing conditions and an inherent inability to socially distance.[64]

60 *Box v. Planned Parenthood of Indiana and Kentucky*, 587 U.S. 490, 494 (2019) (Thomas, J., concurring).

61 Nina Roesner et al., *supra* note 24.

62 Sonia M. Suter, *Why Reason-Based Abortion Bans Are not Eugenic: An Empirical Study*, 10 J.L. & Biosciences 1 (2023).

63 *See*, eg Maya Sabatello & Paul S. Appelbaum, *Behavioral Genetics in Criminal and Civil Courts*, 25 Harv. Rev. Psychiatry 289 (2017).

64 Camila L. Strassle and Benjamin E. Berkman, *Prisons and Pandemics*, 57 San Diego Law Rev. 1083 (2020).

Whatever the topic, such normative analysis is often combined with other research questions highlighted within this paper. For example, following empirical analysis of how the law is impacting the world, a project or paper may add a normative analysis.

III.E.2. Research example 7: understanding how the law is being interpreted and implemented

Legal expertise can offer valuable insights into how the law is interpreted and implemented. Courts, statutes, regulations and other legal documents may use terminology that is potentially subject to different interpretations, which affects how the law is ultimately implemented. Sometimes a legal term or test is ambiguous or not well articulated in the law. But even when terms are defined in a legal ruling or statute, courts and scholars may interpret the terms differently. Legal research can be useful in explaining where there are interpretive disagreements, describing the nature of those disagreements, and discussing the interpretive methodologies that lead to the different understandings of the law. Often such legal analysis does more than just describe the interpretive challenges; it often also provides a normative claim and offers interpretive guidance where there is ambiguity or conflict in interpretations. All of these exercises are important in shaping how a law is ultimately implemented.

One example of this kind of legal analysis is a study that examines how courts have interpreted and implemented the GINA,[65] a federal law passed in 2008 to protect against genetic discrimination in health insurance and employment.[66] One of the contested issues in drafting the law was how to define the term "genetic information." As part of Congress's goal to protect the public "fully" against genetic discrimination,[67] it adopted a broad definition of "genetic information" that includes family history.[68] As the study shows, courts have adopted two different approaches to determining whether information is "genetic information" under GINA.[69] One approach construes "genetic information" in light of GINA's goals to prevent discrimination based on information that indicates a propensity for disease.[70] Although GINA defines "genetic information," in part, as "the manifestation of a disease or disorder in family members" of the individual bringing a GINA discrimination claim,[71] several courts have ruled that certain medical information concerning family members is not "genetic information."[72] As one court stated, the "basic intent" of GINA was "to prohibit employers

65 Suter, *GINA at Ten, supra* note 10.

66 The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110–233, § 2(1), 122 Stat. 881 (noting that scientific advances in human genetics 'give rise to the potential misuse of genetic information to discriminate in health insurance and employment').

67 The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110–233, § 2(5), 122 Stat. 881. The fact that it focused only on discrimination in health insurance and employment undercuts this goal, given that there are risks of discrimination in other sectors such as life insurance, long-term care, insurance, etc. Suter, *GINA at Ten,* supra note 10, at 501–02.

68 Suter, *GINA at Ten, supra* note 10, at 499.

69 *Id.* at 495.

70 *Id.* at 506–07.

71 42 U.S.C. § 2000 (ff)(4) (2023).

72 *See Conner-Goodgame v. Wells Fargo Bank, NA*, 2013 WL 5428448 (N.D. Ala 2013) (finding that plaintiff's mother's AIDS diagnosis was not 'genetic information' in a GINA employment discrimination claim); *Allen v. Verizon Wireless*, 2013 WL 2467923 (D. Conn. 2013) (finding that a family member's disease diagnosis is

from making a "predictive assessment concerning an individual's propensity to get an inheritable genetic disease or disorder based on the occurrence of an inheritable disease or disorder in [a] family member."'[73] Thus, because the medical diagnosis of the wife of an employee suing for employment discrimination was not indicative of the employee's disease risk, the court concluded that her medical information was not genetic information. Such a narrow interpretation makes it harder for GINA discrimination claims to succeed.

Other courts, however, have been willing to treat family member's medical information as 'genetic information' under GINA based solely on the statutory definition and plain meaning of the statute.[74] These courts do not explore whether the information provides predictive information about the plaintiff's health risks.[75] This more capacious understanding of 'genetic information' provides a greater chance for plaintiffs to successfully bring GINA discrimination claims.

This study is not merely descriptive, however. It also argues in favor of the broader interpretation. The author notes there is a 'certain logic' in treating family history as 'genetic information' only when it is predictive of a plaintiff's disease risk because GINA was concerned about discrimination on the basis of the risk of illness. Yet, that understanding ignores unambiguous statutory terms and rejects the interpretive guidance of the Equal Employment Opportunity Commission (EEOC).[76] Not only is the narrower interpretation inconsistent with the plain meaning of GINA, it also deviates 'in subtle and less subtle ways,' from the statute's aim to provide a broad definition of genetic information and to provide 'bright-line rules for enforcement and compliance purposes.'[77] Thus, the project both highlights the interpretive divide and proposes a solution to the disagreement.

IV. CONCLUSION

Legal research follows a variety of robust methods that allow lawyers to address a range of questions for biomedical and ELSI communities, from what the law says about a

'only considered "genetic information" if used to determine the likelihood of disease in another individual' (citing *Poore v. Peterbilt of Bristol*, 852 F. Supp. 2d 727 (2012)); *Maxwell v. Verde Valley Ambulance Co., Inc.*, 2014 WL 4470512 (D. Ariz. 2014) (finding that there was a question of fact as to whether a grandfather's cancer diagnosis provide a predictive information about the plaintiff and therefore was genetic information).

73 *Poore v Peterbilt of Bristol*, 852 F. Supp. 2d 727, 730 (W. D. Va. 2012)(citing H.R. REP. No.110–28, pt. 3, at 70 (2007); 2008 U.S.C.C.A.N. 112, 141).

74 *Jackson v. Regal Beloit America,* No.16–134-DLB-CLS, 2018 WL 3078760 (E.D. Ky. 2018); *Montgomery et al. v. Union Pacific Railroad*, No. CV-17-00201-TUC-RM, 2018 WL 6110930 (D. Ariz. 2018); *Punt v. Kelly Services*, 2016 WL 67654 (D. Colo. 2016) (finding that family history constitutes genetic information); *Lee v. City of Moraine Fire Dept.*, 2015 WL 914440 (S.D. Ohio 2015) (finding that questions from an employer about an employee's family history violates GINA as a request for genetic information); *EEOC v. Grisham Farm Products, Inc.*, 191 F. Supp. 3d 994 (W.D. Mo. 2016) (finding that questions about whether an employee consulted a health care provider or sought health care advice, diagnosis or treatment violated GINA because it could reveal family history.)

75 *See Lowe v. Atlas Logistics Group Retail Serv.*,102 F. Supp. 3d 1360 (N.D. Ga.2015) (treating the results of genetic 'fingerprinting' analysis to identify whether an employee had defecated on the premises, even though it provided no predictive information about the employee's health status).

76 Suter, *GINA at Ten, supra* note 10, at 507.

77 *Id.* at 500. It also adopts the EEOC guidance's views that one of the goals of GINA is to prevent discrimination against employee's based on concerns about higher health care costs or health insurance rates based on an employee's dependents. *Id.* at 508.

particular topic to what the law should say about it. Many research projects with a legal component will tackle several questions, employing multiple legal methods. These inquiries often require detailed and nuanced legal analysis and may necessitate specific expertise in sub-specialty areas of the law. Thus, integrating lawyers into biomedical research projects can help to answer essential questions about how the field is governed both on paper and in practice, can help to translate complex rules into understandable material for the lay public and policymakers alike, and can help establish how laws should be interpreted, implemented and updated.