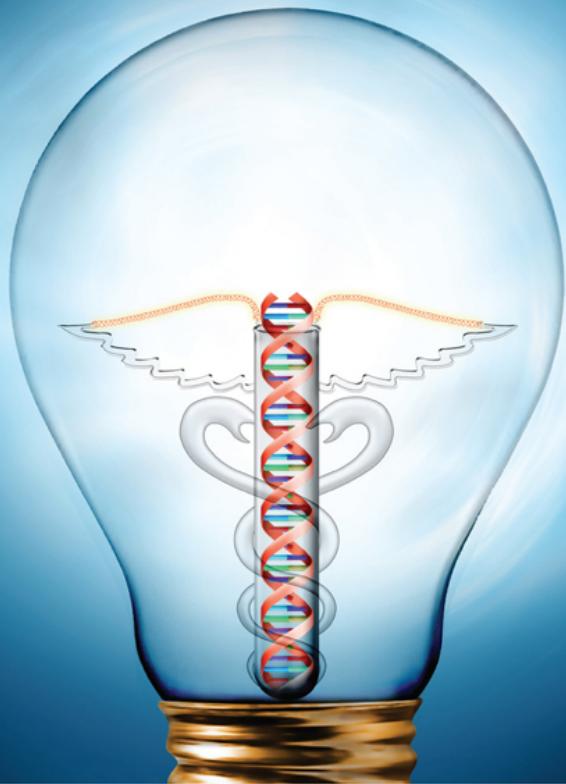


THE JOURNAL OF LAW, MEDICINE & ETHICS

Volume 48:1 • Spring 2020

A Journal of the American Society of Law, Medicine & Ethics • www.aslme.org



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**From “Informed” to “Engaged” Consent:
Risks and Obligations in Consent for
Participation in a Health Data Repository**

*Elizabeth Bromley, Alexandra Mendoza-Graf,
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**Whether to Waive Parental Permission
in HIV Prevention Research Among
Adolescents: Ethical and Legal Considerations**

*Laurie J. Bauman, Claude Ann Mellins,
and Robert Klitzman*

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ISSN: 1073-1105



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Letters to the Editors: Comments on articles in the Journal should be addressed to the Editor at the editorial office or emailed to thutchinson@aslme.org.

Submission Guidelines: For submission guidelines, please contact the editorial office at thutchinson@aslme.org. Submission guidelines are also available online at <http://journals.sagepub.com/home/lme>.

The Journal of Law, Medicine & Ethics (ISSN 1073-1105) (J812) is published quarterly—in March, June, September and December—by SAGE Publishing, 2455 Teller Road, Thousand Oaks, CA 91320 in association with the American Society of Law, Medicine & Ethics. Send address changes to the Journal of Law, Medicine & Ethics, c/o SAGE Publishing, 2455 Teller Road, Thousand Oaks, CA 91320.

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C O N T E N T S

VOLUME 48:1 • SPRING 2020

Symposium Articles

SYMPOSIUM

LawSeq:
Building a
Sound Legal
Foundation
for Translating
Genomics
into Clinical
Application

Guest Edited by
Susan M. Wolf,
Ellen Wright Clayton,
and Frances Lawrenz

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Letter from
the Editor

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Introduction

*Susan M. Wolf, Ellen Wright Clayton,
and Frances Lawrenz*

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**From Genetics to Genomics:
Facing the Liability Implications in
Clinical Care**

*Gary Marchant, Mark Barnes, James
P. Evans, Bonnie LeRoy, and Susan M.
Wolf*

Health care is transitioning from genetics to genomics, in which single-gene testing for diagnosis is being replaced by multi-gene panels, genome-wide sequencing, and other multi-genic tests for disease diagnosis, prediction, prognosis, and treatment. This health care transition is spurring a new set of increased or novel liability risks for health care providers and test laboratories. This article describes this transition in both medical care and liability, and addresses 11 areas of potential increased or novel liability risk, offering recommendations to both health care and legal actors to address and manage those liability risks.

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**How Can Law and Policy Advance
Quality in Genomic Analysis and
Interpretation for Clinical Care?**

*Barbara J. Evans, Gail Javitt, Ralph
Hall, Megan Robertson, Pilar Ossorio,
Susan M. Wolf, Thomas Morgan, and
Ellen Wright Clayton*

Delivering high quality genomics-informed care to patients requires accurate test results whose clinical implications are understood. While other actors, including state agencies, professional organizations, and clinicians, are involved, this article focuses on the extent to which the federal agencies that play the most prominent roles — the Centers for Medicare and Medicaid Services enforcing CLIA and the FDA — effectively ensure that these elements are met and concludes by suggesting possible ways to improve their oversight of genomic testing.

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**Integrating Rules for Genomic
Research, Clinical Care, Public Health
Screening and DTC Testing: Creating
Translational Law for Translational
Genomics**

*Susan M. Wolf, Pilar N. Ossorio,
Susan A. Berry, Henry T. Greely, Amy L.
McGuire, Michelle A. Penny, and
Sharon F. Terry*

Human genomics is a translational field spanning research, clinical care, public health, and direct-to-consumer testing. However, law differs across these domains on issues including liability, consent, promoting quality of analysis and interpretation, and safeguarding privacy. Genomic activities crossing domains can thus encounter confusion and conflicts among these approaches. This paper suggests how to resolve these conflicts while protecting the rights and interests of individuals sequenced. Translational genomics requires this more translational approach to law.

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**Key Expert Stakeholder Perceptions
of the Law of Genomics: Identified
Problems and Potential Solutions**

*Fook Yee Cheung, Lauren Clatch,
Susan M. Wolf, Ellen Wright Clayton,
and Frances Lawrenz*

The law applicable to genomics in the United States is currently in transition and under debate. The rapid evolution of the science, burgeoning clinical research, and growing clinical application pose serious challenges for federal and state law. Although there has been some empirical work in this area, this is the first paper to survey and interview key scientific and legal stakeholders in the field of genomics to help ground identification of the most important legal problems that must be solved to successfully integrate genomics into clinical care. The respondents in this study identified a wide range of interconnected issues, focusing specifically on the need for clear guidelines about how to use these data, fear of liability for those who use these data, and the need to protect patients from use of this information particularly by insurers, while endorsing data sharing. Developing legal strategies to support appropriate use of genomics now and in the future clearly will require making trade-offs, taking into account the full complexity of this legal ecosystem.

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The Streetlight Effect: Regulating Genomics Where the Light Is

Barbara J. Evans

Regulatory policy for genomic testing may be subject to biases that favor reliance on existing regulatory frameworks even when those frameworks carry unintended legal consequences or may be poorly tailored to the challenges genomic testing presents. This article explores three examples drawn from genetic privacy regulation, oversight of clinical uses of genomic information, and regulation of genomic software. Overreliance on expedient regulatory approaches has a potential to undercut complete and durable solutions.

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The Implementation Chasm Hindering Genome-informed Health Care

Kevin B. Johnson, Ellen Wright Clayton, Justin Starren, and Josh Peterson

The promises of precision medicine are often heralded in the medical and lay literature, but routine integration of genomics in clinical practice is still limited. While the “last mile” infrastructure to bring genomics to the bedside has been demonstrated in some healthcare settings, a number of challenges remain — both in the receptivity of today’s health system and in its technical and educational readiness to respond to this evolution in care. To improve the impact of genomics on health and disease management, we will need to integrate both new knowledge and new care processes into existing workflows. This change will be onerous and time-consuming, but hopefully valuable to the provision of high quality, economically feasible care worldwide.

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Protecting Participants in Genomic Research: Understanding the “Web of Protections” Afforded by Federal and State Law

Leslie E. Wolf, Catherine M. Hammack, Erin Fuse Brown, Kathleen M. Brelsford, and Laura M. Beskow

Researchers now commonly collect biospecimens for genomic analysis together with information from mobile devices and electronic health records. This rich combination of data creates new opportunities for understanding and addressing important health issues, but also intensifies challenges to privacy and confidentiality. Here, we elucidate the “web” of legal protections for precision medicine research by integrating findings from qualitative interviews with structured legal research and applying them to realistic research scenarios involving various privacy threats.

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General-Purpose Privacy Regulation and Translational Genomics

William McGeeveran and Caroline Schmitz

At one time, specialized health privacy laws represented the bulk of the rules regulating genetic privacy. Today, however, as both the field of genomics and the content of privacy law change rapidly, a new generation of general-purpose privacy laws may impose new restrictions on collection, storage, and disclosure of genetic data. This article surveys these laws and considers implications.

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The Future of DTC Genomics and the Law

Henry T. Greely

Direct-to-Consumer (“DTC”) genomics has been a controversial topic for over a decade. Much work has been done on the legal issues it raises. This article asks a different question: What will DTC genomics and its legal issues look like in ten to twenty years? After discussing the five current uses of DTC genomics, it describes three current legal issues: medical uses, privacy of genomic information, and privacy in collection and analysis of human DNA. It then suggests that changes in human genomics and how it is used will make the first of those DTC genomics legal issues less important in the future, but that the third will be increasingly significant.

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A Right to Privacy and Confidentiality: Ethical Medical Care for Patients in United States Immigration Detention

*Amanda M. Gutierrez, Jacob D. Hofstetter,
Emma L. Dishner, Elizabeth Chiao, Dilreet
Rai, and Amy L. McGuire*

Recently, John Doe, an undocumented immigrant who was detained by United States Immigration and Customs Enforcement (ICE), was admitted to a hospital off-site from a detention facility. Custodial officers accompanied Mr. Doe into the exam room and refused to leave as physicians examined him. In this analysis, we examine the ethical dilemmas this case brings to light concerning the treatment of patients in immigration detention and their rights to privacy. We analyze what US law and immigration detention standards allow regarding immigration enforcement or custodial officers' presence in medical exams and documentation of detainee health information. We describe the ethical implications of the presence of officers in medical exam rooms, including its effects on the quality of the patient-provider relationship, patient privacy and confidentiality, and provider's ability to provide ethical care. We conclude that the presence of immigration enforcement or custodial officers during medical examination of detainees is a breach of the right to privacy of detainees who are not an obvious threat to the public. We urge ICE and the US Department of Homeland Security to clarify standards for and tighten enforcement around when officers are legally allowed to be stationed in medical exam rooms and document detainees' information.

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From "Informed" to "Engaged" Consent: Risks and Obligations in Consent for Participation in a Health Data Repository

*Elizabeth Bromley, Alexandra Mendoza-
Graf, Sandra Berry, Camille Nebeker, and
Dmitry Khodyakov*

The development and use of large and dynamic health data repositories designed to support research pose challenges to traditional informed consent models. We used semi-structured interviewing (n=44) to elicit diverse research stakeholders' views of a model of consent appropriate to participation in initiatives that entail collection, long-term storage, and under-terminated future research use of multiple types of health data. We demonstrate that, when considering health data repositories, research stakeholders replace a concept of consent as informed with one in which consent is engaged. In engaged consent, a participant's ongoing relationship with a repository serves as a substitute or adjunct to information exchange at enrollment. We detail research stakeholders' views of the risks of engaged consent and suggest questions for further study

about engagement and consent procedures in initiatives that aim to store data for future unspecified research purposes.

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Whether to Waive Parental Permission in HIV Prevention Research Among Adolescents: Ethical and Legal Considerations

*Laurie J Bauman, Claude Ann Mellins,
and Robert Klitzman*

Critical ethical questions arise concerning whether studies among adolescents of new behavioral and biomedical HIV preventive interventions such as Pre-Exposure Prophylaxis (PrEP) should obtain parental permission. This paper examines the relevant regulations and ethical guidance concerning waivers of parental permission, and arguments for and against such waivers. Opponents of such waivers may argue that adolescent decision-making is "too immature" and that parents always have rights to decide how to protect their children. Yet requiring parental permission may put adolescents at risk, and/or limit adolescent participation, jeopardizing study findings' validity. This paper presents recommendations on when researchers and Institutional Review Boards (IRB) should waive parental permission, and what special protections should be adopted for adolescents who consent for themselves, e.g., assuring adolescent privacy and confidentiality, screening for capacity to consent, and identifying adolescents who are at elevated risk from study participation. We also present a series of specific areas for future research to design tools to help make these assessments, and to inform researcher and IRB decisions. These recommendations can help ensure that research is conducted that can aid adolescents at risk for HIV, while minimizing risks and protecting these individuals' rights as much as possible.

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Quianta Moore and Zeinab Bakhiet

Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

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Australian Aboriginal and Torres Strait Islander Collections of Genetic Heritage: The Legal, Ethical and Practical Considerations of a Dynamic Consent Approach to Decision Making

Megan Prictor, Sharon Huebner, Harriet J.A. Teare, Luke Burchill, and Jane Kaye

Dynamic Consent (DC) is both a model and a specific web-based tool that enables clear, granular communication and recording of participant consent choices over time. The DC model enables individuals to know and to decide how personal research information is being used and provides a way in which to exercise legal rights provided in privacy and data protection law. The DC tool is flexible and responsive, enabling legal and ethical requirements in research data sharing to be met and for online health information to be maintained. DC has been used in rare diseases and genomics, to enable people to control and express their preferences regarding their own data. However, DC has never been explored in relationship to historical collections of bioscientific and genetic heritage or to contexts involving Aboriginal and Torres Strait Islander people (First Peoples of Australia).

In response to the growing interest by First Peoples throughout Australia in genetic and genomic research, and the increasing number of invitations from researchers to participate in community health and wellbeing projects, this article examines the legal and ethical attributes and challenges of DC in these contexts. It also explores opportunities for including First Peoples' cultural perspectives, governance, and leadership as a method for defining (or redefining) DC on cultural terms that engage best practice research and data analysis as well as respect for meaningful and longitudinal individual and family participation.

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