Proposed By: Jennifer K. Wagner, JD, PhD

Proposed Moderator(s): Jennifer K. Wagner, JD, PhD

Session Topic Area: 10. Ethical, Legal, Social and Policy Issues in Genetics

Session Content: Social Issues

Session Title: Unusual Suspects: A Legal Line-Up Beyond GINA

Session Description:
The legal implications of genetic/genomic research and the practice of precision medicine are many. By now most ASHG members are familiar with the Genetic Information Nondiscrimination Act of 2008, the United States law that prohibits acquisition and use of genetic information in health insurance and employment decisions. But other legal issues remain sources of mystery and uncertainty. An ignorance of "the law" has the potential to thwart the hard work of researchers with even the best intentions and most innovative ideas. This session will showcase four ELSI scholars who will discuss serious legal issues in four key areas: legal pressures in the practice of medicine, data sharing policy considerations for precision medicine, regulatory oversight for research with human participants, and legal process for law enforcement and third-parties to gain access to genomic databases (proprietary, confidential, or otherwise).

Session Rationale:
This session was carefully designed for ASHG. The 2016 membership year is the first the proposer is transitioning from trainee to regular member status. The session includes a Canadian speaker, which is an important aspect given the site for the meeting, and includes presentation topics that all have international relevance. The panel of speakers features an equal number of female and male speakers as well as representation of speakers who are early in career (JKW and MNM) and more established (BCD and TC). While few legal and policy scholars are members of ASHG, this session was able to include two ASHG members (BCD and JKW). A fifth speaker (WNP) is listed as an alternate to highlight that there are a tremendous number of legal and policy areas that deserve ASHG attention. The session topics address gaps in knowledge for ASHG members on laws and policy that impact their work. For example, even experts on research oversight and regulatory compliance have struggled to understand the NPRM for the Common Rule. The topics chosen for this session were selected in part because ASHG members and non-members frequently ask these questions when speaking to the proposer. Furthermore, this session was intentionally designed as a broad session to cover a range of diverse issues to appeal to the broadest audience possible. A narrowly focused session in one legal area was considered during the development of this session; however, such a session would be less likely to draw a sizeable audience and the deep discussion it could generate might seem like material too advanced for the audience and would neglect the overarching goal of this session, i.e., to highlight there are more legal issues for ASHG members to consider than the health insurance and employment nondiscrimination provisions of the Genetic Information Nondiscrimination Act. Finally, it is important for ASHG members to have exposure to legal and policy scholars to ask questions outside of their own institutions' legal departments (where responses are known to be biased by risk management priorities), and this session would provide an opportunity to help members understand disruptive innovations can occur in law and policy as well as science and technology. A sound understanding of the law and policy will empower ASHG members by making them more prepared to address the issues in their research design and also promote their ability to help shape laws and policies rather than be passively bound by them, frustrated by them, or surprised by them.

Learning Objectives
1. Explain and improve understanding of the legal and normative pressures that exist in the coming era of precision medicine.
2. Identify and analyze emerging data sharing policies and to recognize the legal implications of a "commons" and governance challenges for genetics research and practice.
3. Clarify the dramatic changes to research oversight signaled by the Notice of Public Rule Making for the Common Rule (NPRM) and critically analyze the federal policy's development and impact on the future of genetic/omic research.
4. Examine how law enforcement and third-parties can use legal process to gain access to participant, patient, or DTC customer information (regardless of assurances of privacy or confidentiality) and to clarify when, how, and to what extent databases could be shielded by NIH Certificates of Confidentiality.

Attendee Benefits:
Attendees will gain an improved awareness of laws and policies other than the Genetic Information Nondiscrimination Act. Attendees will learn how these issues affect them in society broadly as well as in their own research and practice.

Target Audience:
All members of ASHG at all career stages would benefit from this session. No experience with law or policy is necessary. It is anticipated that the topics - which involve basic research, clinical research, practice of medicine, and direct-to-consumer/industry considerations - would have broad appeal.

The competencies and attributes the session will address:
Patient Care
Medical Knowledge
Practice-Based Learning
Interpersonal and communication skills
System-based Practice

Other: legal reasoning, policy analysis, and ethical literacy

Speaker 1: Timothy Caulfield, LLB, LLM
Presentation Title: “Legal Norms, Defensive Medicine and Personalized Medicine”
Presentation Content: Much has been made about the potential health and health system benefits of personalized medicine. At the core is the idea that it a more targeted approach will result in better care, with fewer side effect and more efficient systems. While there is certainly great potential, there are reasons to believe that existing legal norms may complicate the implementation of personalized approaches, particularly in the context of cost. This talk will review the various legal challenges – such as liability pressures, concern about meeting existing standards of care, satisfying fiduciary relationship, etc. – and what the available evidence suggests about how they may impact healthcare provider behaviour, particularly in the context of targeted therapies and genetic testing.

Speaker 2: Robert Cook-Deegan, MD
Presentation Title: “Obstacles to Building a Medical Information Commons”
Presentation Content: Building a Medical Information Commons for the Precision Medicine Initiative, and as envisioned by the National Academies, will require data-sharing well beyond current practice. Extracting scientific meaning and interpreting the clinical significance of human genetic variation requires access to data not only about DNA sequence, but also genealogy, clinical outcomes, environmental exposures, and medical records. Full understanding depends on data from populations around the globe. The benefits of data-sharing contend with incentives not to share, including costs of sharing, loss of proprietary advantage, national laws governing export of data and samples, potential liability, and privacy protections. Policy options to promote sharing include: rules for publication that ensure replicability, rules of accreditation or certification of genetics professionals or laboratories, regulatory approval contingent on verifiability of medical claims, and coverage and reimbursement conditional on data-sharing.

Speaker 3: Michelle N. Meyer, PhD, JD
Presentation Title: “How Meaningful Is ‘Choice’ Without Education?: Mandated Choice Over Participation in Biospecimens Research in a Time of Misfearing and Regulatory Confusion”
Presentation Content: For the first time in over three decades, regulators will overhaul the so-called Common Rule, the federal law that governs research with human subjects. Perhaps the most dramatic proposed revision is to the governance of biospecimens research. The proposed rule would alter the regulatory definition of “human subject” itself to render for the first time any research use of a human biospecimen—regardless of its identifiability—to constitute research with a human subject requiring (with narrow exceptions) informed consent. The case for the proposed rule rests on the risk of re-identification, the importance of allowing people to say no to participation in biospecimens research (at issue in the Henrietta Lacks and newborn blood spots cases), and in particular to allowing them to say no to particular research uses to which they object (at issue in the Havasupai case), and the importance to the research enterprise of public trust. Yet the new rule requires only “broad consent” to future, unspecified research. It asks patients to make this choice against a background of inadequate education about, and often “misfearing” over, science in general and genetics in particular, without any corresponding commitment to educate the public about the importance and ubiquity of biospecimens research or the what we can and cannot know about someone on the basis of their biospecimens or their genomic data. And it inexplicably would require no consent for research conducted on data, including WES/WGS data, derived from clinical biospecimens. This talk will provide an overview of federal law governing biospecimens research as it exists in October 2016. It will then discuss a range of governance options over research with biospecimens and genomic data, from notice and opt-out to broad consent to tiered (“checklist”) consent, and the role of education and of various values (autonomy, welfare, and solidarity) in each.

Speaker 4: Jennifer K. Wagner, JD, PhD
Presentation Title: “Ready or not, here they come: law enforcement and third-party access to genomic databases”
Presentation Content: When Wired reported its story “Your Relative’s DNA Could Turn You Into a Suspect” in October 2015, it grabbed the public’s attention with its account that cops have been requesting access to 23andMe and AncestryDNA member information for use with familial searches. Derivative stories quickly popped up in a wide range of venues, including the ABA Journal. While familial searching techniques continue to accumulate science and policy critics alike and while matters of privacy and confidentiality have dominated genomic policy discussions, the reaction to these recent reports have highlighted that many—researchers; prospective, current, and former research participants; and DTC customers—do not have a clear understanding about legal processes for discovery and the compelled disclosure scenarios that are possible. Researchers have attempted to assuage the anxiety of research participants by promising privacy or confidentiality will be maintained to the fullest extent possible or to the extent required under law. Some researchers have obtained NIH Certificates of Confidentiality as added protection to shield themselves and their research participants from compelled disclosures for “sensitive” research. DTC providers have included germane provisions in terms of service and privacy policies. Yet there are always exceptions to the rules, boundaries to be set, limits to confidentiality in practice, and fine print to be acknowledged. This talk will provide legal updates and insights to empower attendees to handle these issues proactively in practice and policy.