

P5. Biomedical Innovation and Regulation

23 rd ASLI Conference 2026		
Panel Category	:	Health Law
Panel Title	:	Biomedical Innovation and Regulation
Panel Abstract	:	
<p>The pace of biomedical innovation across Asia is relentless as more jurisdictions pour greater resources into biomedical research and encourage biomedical innovation in their health care systems to address unmet medical and public health needs. This panel examines various legal and regulatory developments, strategies and challenges concerning genomic medicine research, new reproductive technologies, fast tracking ethics review of innovative therapies and off-label prescriptions in Japan and Singapore.</p>		

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Name of Convenor	:	Tracey Evans Chan
Designation / Academic Post	:	Full-Time Professor
Institution / Organisation	:	National University of Singapore, Faculty of Law
Title of Paper		
The Oversight of Off-Label Prescriptions: Recent Developments in Singapore		
<p>Off-label prescriptions of drugs or devices have been described as an integral part of medical practice. This involves prescriptions for indications or patient populations that are not indicated in the drug or device's registration and extends to dosages or methods of administration beyond label specifications. The Singapore courts have recently disciplined medical practitioners for professional misconduct involving various forms of off-label prescriptions. In doing so, they have articulated clearer standards expected of doctors in Singapore in relation to this clinical phenomenon. The presentation will examine the legal principles, ethics and implications of the decisions and situate the issues within the larger regulatory framework in relation to the use of drugs and devices. It will consider if further reforms are needed to bolster the protection of patients while encouraging off-label prescriptions that further the best interests of patients and the public health interest.</p>		
Brief Biography of Author		
<p>Tracey Evans Chan is an Associate Professor in the Faculty of Law, National University of Singapore, and specialises in biomedical law and ethics. He has published in the field both locally and internationally, and served in a number of Singapore expert committees on matters such as surrogacy, transplant ethics, human-animal combinations in biomedical research and mitochondrial germline modification. He currently sits on the Singapore Ministry of Health's National Medical Ethics Committee and NUS's Institutional Review Board.</p>		

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Name of Panelist	:	Yukio Sakurai
Designation / Academic Post	:	Ph.D.
Institution / Organisation	:	Yokohama National University
Title of Paper		
Legislative and Administrative Challenges in Japan's Genome Medicine Research Law: Aligning National Medical Policy and Ethical Governance with Medical Innovation		
Abstract		
<p>This study examines the dual challenges of legislating and implementing Japan's Genome Medicine Research Law of 2023, focusing on the intersection of medical policy, ethical governance, and technological innovation. The law aims to regulate the rapid advancement of genomic technologies by balancing scientific progress with ethical and legal safeguards grounded in national medical policy. However, the legislative process exposed enduring tensions among divergent bioethical perspectives and stakeholder interests, hindering the establishment of a coherent and robust legal framework. Following enactment, administrative authorities have encountered significant difficulties in developing and executing the government's Basic Plan, particularly in addressing unresolved issues of genetic privacy, data sharing, and governance mechanisms essential for responsible genomic research and clinical practice. Notably, the Basic Plan has remained unformulated for more than two years after the law's enactment—an unprecedented delay in Japan's health policy governance. This study proposes a framework for reconciling these legislative and administrative challenges through enhanced coordination among governmental agencies, academic institutions, and the private sector, underpinned by ethical integrity and legal-policy coherence. It advances a governance model that harmonizes medical innovation with accountability, ensuring that the development of genome medicine research contributes to public health objectives without compromising core bioethical principles. The research further underscores the need for independent multidisciplinary oversight and international collaboration to promote transparency, trust, and sustainable governance in this evolving field.</p>		
Brief Biography of Author		
<p>Yukio Sakurai, Doctor of Laws, is a collaborative researcher at Yokohama National University and a member of the European Law Institute (Vienna). He holds a Doctor of Laws (Yokohama National University, 2022), a Master of Medical Administration (Institute of Science Tokyo, 2025), an MBA in Social Design Studies (Rikkyo University, 2017), and a Bachelor of Laws (The University of Tokyo, 1980). His research focuses on elder law, health policy, and global governance, pursued as a lifelong academic commitment. He is the author of the book: End-of-Life Decision Making in East Asia: Legal Challenges, Cultural Norms, and Advance Planning (Common Ground Research Network, 2025). doi:10.18848/978-1-966214-77-9/CGP. His principal publications and research profile are available via ORCID: https://orcid.org/0000-0003-1273-9227.</p>		

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Name of Panelist	:	Ryan Friets
Designation / Academic Post	:	Ph.D. Candidates
Institution / Organisation	:	National University of Singapore, Centre for Biomedical Ethics
Title of Paper		
A Brief Review of Justification for Reproductive Technology Regulation in Singapore		
Abstract		
<p>In Singapore, most reproductive technology is regulated by specific legislation or guidelines. This paper reviews five sets of reproductive medicine regulations in Singapore to determine what the driving justifications are for their enactment:</p> <ol style="list-style-type: none">1) Social egg freezing2) Preimplantation genetic testing3) Non-invasive prenatal testing4) Reproductive carrier screening5) Mitochondrial gene replacement technology <p>By determining the driving justifications behind each set of regulations, it becomes clearer what the priorities of policymakers in Singapore are when formulating reproductive medicine regulations. This will then inform the likely way in which future technologies will be regulated in Singapore.</p> <p>In formulating regulations, policymakers have four main considerations: These main considerations are the enhancing of reproductive autonomy, adherence to the rule of law, the promotion of public health and public interest, and managing the expressivist objection (this is particularly so for reproductive testing technologies).</p> <p>Each of these is weighed differently for each set of regulations, but not in such a distinct way that they are unable to form a coherent framework for reproductive technology regulation as a whole. Based on this analysis, promoting reproductive autonomy is heavily prioritised as a driving justification for the implementation and regulation of many of the technologies. However, the other competing considerations that interact to shape the limits of each regulation, as would be the case in a pluralistic system such as Singapore. Therefore, it is likely that when formulating future policy, such as for expanded non-invasive prenatal testing, regulators would bear in mind similar considerations as a starting point.</p>		
Brief Biography of Author		
<p>Ryan is a PhD student at the Yong Loo Lin School of Medicine, National University of Singapore. He holds a BA in Jurisprudence from the University of Oxford, as well as an MA in Medical Ethics and Law from Kings' College London. His dissertation focused on the implications of Non-Invasive Prenatal Testing in public healthcare settings, focusing primary on informed consent and patient autonomy. His thesis focuses on the regulation of expanded non-invasive prenatal testing involving sequencing the foetal genome in Singapore. His research interests include the regulation of emerging medical technologies and other areas involving the intersect between law and ethics.</p>		

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Name of Panelist	:	Mathavi Senguttuvan
Designation / Academic Post	:	Full-Time Researcher
Institution / Organisation	:	National University of Singapore, Centre for Biomedical Ethics

Title of Paper

'Fast-Track' Ethics Review: The Singapore Model for Governing Innovative Therapies

Abstract

As part of an expansive overhaul of its legal landscape pertaining to healthcare, Singapore has recently adopted a distinctive regulatory pathway for providing 'innovative treatments'. A specified list of 'prescribed medical treatments' under section 26 of the Healthcare Services Act 2020 (HCSA) can be provided to patients only if their cases have been reviewed by a Clinical Ethics Committee (CEC), which must be satisfied that the treatment would be ethically appropriate. While this model effectively transforms CECs from advisory bodies into adjudicatory 'gatekeepers' for expanded/compassionate access to prescribed treatments, it can accelerate potentially life-saving care by circumventing the bottlenecks associated with full clinical-trial pathways ordinarily required before providing these treatments to the general population.

However, this route seems to redistribute risk and accountability in the absence of an appeals process or adequate clarity around legal liability for decisions rendered by the committees. Concerns can also be raised around the sustainability of the model in the long run, given the greater need for technical expertise in reviewing such cases, potential for 'rubber-stamping', etc.

This paper undertakes a doctrinal and normative analysis of this novel approach which brings ethics review into the fold without compromising on access, situating it alongside the existing Special Access Routes (SAR) administered by the Health Sciences Authority, and other mechanisms in place for accessing unregistered/novel therapies. It argues for reinforcing the CEC pathway's palpable commitment to justice in access and efficiency, with guardrails to ensure legitimacy and safety, harmonised guidance, and appellate mechanisms to ensure due process.

Brief Biography of Author

Mathavi Senguttuvan is a Research Associate with the Clinical Ethics Network + Research Ethics Support (CENTRES) programme at the Centre for Biomedical Ethics, NUS Yong Loo Lin School of Medicine. A lawyer by training, she holds a B.A., LL.B. (Hons) from the National Law School of India University, Bangalore and an LL.M. from the NUS Faculty of Law. She is also in the process of completing her PhD with the centre, focusing on postcolonial discourses on vulnerability and migration in the public health setting.