WYNG-Hatton Lecture 2023:
Smart Regulation for Medical Innovation

Monday 19:00-20:30

Medical innovation is desirable for clinical and economic reasons, but there is no consensus on the best regulatory approach to promote it. The paradigm for the regulation of medical research is a gatekeeping system but in the era of increasingly personalised medicine and rapid technological development, this is perceived by some as an anachronistic barrier to scientific advance, an unjustified bureaucratic cost, and a mechanism that frustrates consumer expectations. Yet, in the absence of the regulatory protection that obtaining permission provides, patients may face unacceptable risks and innovators are exposed to unreasonable risk of civil and criminal liability should mishaps occur. A series of UK court decisions on innovative treatments for young people, including Pentosan Polysulphate treatment for nvCJD (Simms), Proton Beam Therapy (King) nucleoside therapy (Gard), puberty blockers (Tavistock) have exposed the vices that undermine trust in innovation but also help us to identify the virtues that responsible innovators should display. Smart regulation is required to promote those virtues without creating unnecessary bureaucratic hurdles. An unwieldy system of prior ethics committee approval can be avoided if we can use markers of trustworthiness as a basis of the licence to innovate.

Sir Jonathan Montgomery

Professor of Health Care Law, Faculty of Laws, University College London;
Chair, Ethics Advisory Committee of Genomics England

As Chair of the Health Research Authority (2012-19) he was responsible for the oversight of research ethics approvals in England; working to reduce regulatory complexity and improve research integrity in order to protect the interests of the public, participants and patients. He was Chair of the Nuffield Council on Bioethics, the UK's national ethics committee, from 2012-17 and of the UK Human Genetics Commission from 2009-12. During the COVID pandemic, he was co-chair of the Moral and Ethical Advisory Group to the UK Chief Medical Officers and chair of the Ethics Advisory Board to NHSX on its Contact Tracing App. He was elected Honorary Fellow of the Royal College of Paediatrics and Child Health in 2005, Honorary Fellow of the Faculty of Public Health in 2023, and Fellow of the Academy of Medical Sciences in 2021. He was made Knight Batchelor for services to Bioethics and Health Care Law in the 2019 New Years Honours.

Commentators:

Wei Zhu · 朱伟

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Dr Wei ZHU is Associate Professor at Center for Applied Ethics, Fudan University and Vice-Chair of Shanghai Ethics Committee for Clinical Research (SECCR). She is also Fellow of the Hastings Center, the U. S. A and Guest Professor at Center for Ethical Studies, Renmin University of China. She has a background in bioethics, with specific training and expertise in research ethics and ethical oversight systems for research in developing countries. Her research areas include genetic ethics, informed consent in multi-cultural context, justice in health resource distribution and human rights. She is the member of several ERBs at Fudan University and other major hospitals and research

institutions. She is currently working on two research ethics projects (PREPARED and iRECS), which is sponsored by HORIZON.

Ping Ji・吉萍

Deputy Director, Clinical Research Institute, Shenzhen-Peking University-The Hong Kong University of Science and Technology Medical Center, Shenzhen

Dr Ping Ji began her clinical research career as medical writer and monitor for industry in China after obtaining her PhD in 2006 at Cardiff University, UK. She developed her interests in medical research ethical review and human subjects protection since 2010. She took the role as director of Quality Assurance Office in Peking University Human Research Protection Program by 2016. Since 2016, she moved to Shenzhen for building clinical research support and supervision platforms for education & training, technological support, ethical review, and policy development with the support from the local health authority. Together with her colleagues, her team has made great achievements on developing regional clinical research infrastructure.