Challenges in regulating biomedical research: The Human Subjects Research Act and the Human Biobank Management Act in Taiwan

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Abstract

Regulating human subject research has proved a challenge to regulators around the world as they must find the most appropriate ways to regulate scientists while also avoiding both over-regulation and under-regulation. Two new laws, the Human Subjects Research Act of 2011 and the Human Biobank Management Act of 2010, mark a milestone in the regulation of human research in Taiwan. The former derives from government-issued ethical guidelines of the past decade and provides core rules for the general governance of human subject research while also giving institutional review boards (IRBs) legal status and authority and requiring them to be subject to government inspection. In the past two and half years, 79 IRBs have been approved by the Ministry of Health and Welfare, and the funding agency and research community, including biomedical and socio-behavior researchers, have brought their practice into line with the new law.

The Human Biobank Management Act, in turn, addresses public concerns by stipulating high standards for the setting up of biobanks. Nineteen biobanks, mostly in large hospitals (e.g. disease biobanks), have been formed and have received government certification. The new Act also applies biobank standards to the regulation of other types of specimen collection activities, unrelated to biobanking, and to pre-existing specimens. This broad coverage has provoked furious debate, resulting in an amendment to the Act to narrow its coverage.

Key words

research ethics, human subject, biobank, biomedical research, legislation

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