

Biomedical Laws & Ethics

The success of the Human Genome Project at the start of this millennium has triggered the development of many new medical technologies, from stem cell therapies and nanomedicine, to highly personalized diagnostics and theranostics.

In 2007, the Ministry of Health issued the Governance Framework for Human Biomedical Research. The Governance Framework draws from various guidelines and regulations such as the Medicines (Clinical Trials) Regulations, the National Medical Ethics Committee's ethical guidelines on research involving humans, and various reports of the Singapore Bioethics Advisory Committee.

The BAC formulates guidelines and policies to address the ethical, legal and social issues arising from biomedical sciences research in Singapore. It has, to date, published nine consultation papers, spanning a range of topics, such as "Human-Animal Combinations for Biomedical Research" and "Ethical, Legal and Social Issues in Neuroscience Research", amongst others.

In 2015, the Human Biomedical Research Act came into force.

Organisations and individuals engaging in human biomedical research now have greater clarity on their roles and responsibilities in this rapidly evolving field.

Awards & Accolades

Band 1 for Life Sciences

Chambers Asia Pacific 2014 - 2024

Medical and Healthcare Law Firm of the Year

Asian Legal Business Southeast Asia Law Awards 2020 and 2021

Band 1 for Intellectual Property

Chambers Global 2009 - 2024

Band 1 for Intellectual Property

Chambers Asia Pacific 2010 - 2024

Tier 1 for Intellectual Property

Legal 500 Asia Pacific 2010 - 2024

Tier 1 for Patents and Copyrights/
Trademarks in Singapore

ALB Asia IP Rankings 2018 - 2024

Asia Pacific Patents Firm of the Year

Asia IP Law 2023

Tier 1 for Copyright, Trademark
Contentious and Trademark Prosecution in
Singapore

Asia IP Law 2023

Asia Pacific IP Firm of the Year

**Managing IP Asia Pacific Awards
2018 - 2022**

Global IP Firm of the Year

**Managing IP Asia Pacific Awards
2017, 2018 and 2022**

Human Biomedical Research Act

The Act clarifies the roles and responsibilities of organisations and individuals which engage in research involving human subjects to notify the MOH and comply with other requirements set out in the Act, in order to be established as a "research institution" for the purposes of the Act.

Further, it aims to better protect the welfare of research participants and tissue donors and prohibit the commercial trading of human tissues, regardless of whether these are used in research. This is to ensure that such research, tissue collection and storage are carried out under sound research and ethical practices and principles.

Regulations in the Act apply to the following two research areas:

1. Restricted – MOH's approval is required for the introduction of human genes into an animal embryo; and
2. Prohibited
 - a) The development of human-animal embryos beyond 14 days; and
 - b) The insertion of human stem cells into the brains of apes.

The Act also includes rules on the use of donated tissues, such as:

- a) A written consent form is needed before the donor's tissue is removed;
- b) Donors can elect to give their tissues for generic or specific research use;
- c) A tissue bank must notify the MOH before banking any tissue to ensure that the donor's tissues are handled safely;
- d) A Person-in-Charge must also be appointed to develop clear policies to monitor, supervise and review the conduct of banking tissues; and
- e) For vulnerable groups such as young donors or adult donors who lack the mental capacity to provide consent, a guardian or parent can give their consent for them, provided that the removed tissue is primarily used for diagnostic or therapeutic purposes.

Existing laws prohibiting the sale of human organs or embryos, such as the Human Organ Transplant Act and the Human Cloning and Prohibited Practices Act continue to be in force.

Although companies are not regulated by the Singapore Medical Council Ethical Code, compliance with the SMC Code may help to show a lack of "corrupt intent" on the company's part, for the purposes of the Prevention of Corruption Act. It may also mitigate the risk of the Singapore Medical Council sanctioning doctors whom the company had interacted with, and accordingly may reduce the company's exposure to negative publicity.

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