

REPUBLIC OF SINGAPORE

GOVERNMENT GAZETTE

BILLS SUPPLEMENT

Published by Authority

NO. 25] MONDAY, JULY 13 [2015

First published in the Government Gazette, Electronic Edition, on 13th July 2015 at 5:00 pm.

Notification No. B 25 — The Human Biomedical Research Bill is hereby published for general information. It was introduced in Parliament on 13th July 2015.

Human Biomedical Research Bill

Bill No. 25/2015.

Read the first time on 13 July 2015.

HUMAN BIOMEDICAL RESEARCH ACT 2015

(No. of 2015)

ARRANGEMENT OF SECTIONS

PART 1

PRELIMINARY

Section

- 1. Short title and commencement
- 2. General interpretation
- 3. Meanings of "human biomedical research" and "supervision and control"

PART 2

ADMINISTRATION OF ACT

- 4. Administration of Act
- 5. Advisory committees

PART 3

CONSENT

- 6. Taking of appropriate consent
- 7. Consent for research involving adults who lack mental capacity
- 8. Consent for research involving minors
- 9. Consent for removal or use of tissue for research involving adults who lack mental capacity
- 10. Consent for removal or use of tissue for research from minors
- 11. Consent for research or removal or use of tissue for research in case of deceased persons
- 12. Information to be provided before taking appropriate consent

Section

- 13. Waiver of appropriate consent by institutional review board
- 14. Withdrawal of consent

PART 4

INSTITUTIONAL REVIEW BOARDS

- 15. Appointment and notification of institutional review boards
- 16. Appointment of institutional review boards by multiple research institutions
- 17. Functions and duties of institutional review boards
- 18. Composition, quorum and proceedings of institutional review board
- 19. Conflicts of interest
- 20. Application to institutional review board for review
- 21. Appeal against decision of institutional review board

PART 5

REGULATION OF HUMAN BIOMEDICAL RESEARCH

- 22. Conduct of human biomedical research and duties of researcher
- 23. Functions and duties of research institutions
- 24. Declaration of compliance by research institution
- 25. Appropriate consent from research subjects
- 26. Compelling person to participate in research
- 27. Duty to protect health information and human biological material against loss, unauthorised disclosure, etc.
- 28. No re-identification of anonymised information or biological material without consent
- 29. Restrictions on disclosure of information
- 30. Prohibited human biomedical research
- 31. Restricted human biomedical research

PART 6

REGULATION OF HUMAN TISSUE ACTIVITIES AND TISSUE BANKS

- 32. Commercial trading of human tissue prohibited
- 33. Advertisements relating to commercial trading of human tissue prohibited
- 34. Notification of tissue bank
- 35. Duties of tissue bank

Section

- 36. Declaration of compliance by tissue bank
- 37. Restrictions on activities relating to human tissue
- 38. Compelling person to donate tissue
- 39. Restrictions on disclosure of information on tissue donor

PART 7

CODES OF PRACTICE AND ETHICS

- 40. Codes of practice or ethics
- 41. Use of codes of practice or ethics

PART 8

ENFORCEMENT POWERS

- 42. Immediate stoppage of human biomedical research or tissue banking activity, etc.
- 43. Prohibiting person from conducting research or tissue banking activities
- 44. Review of prohibition order
- 45. Powers of entry, inspection and search, etc.
- 46. Disposal of articles or documents
- 47. Information and identity of informers not to be disclosed
- 48. Minister may appoint committee of inquiry under Inquiries Act
- 49. Protected information
- 50. Enhanced penalty for corporations
- 51. Liability of employers for acts of employees
- 52. Offences by bodies corporate, etc.
- 53. Composition of offences

PART 9

APPEALS

- 54. Appeal to Minister
- 55. Appeals Advisory Panel

PART 10

MISCELLANEOUS

- 56. Act binds Government
- 57. Power to exempt
- 58. Designation of persons by Minister

Section

- 59. Service of documents
- 60. Jurisdiction of courts
- 61. Protection from personal liability
- 62. Amendment of Schedules
- 63. Regulations
- 64. Savings and transitional provisions for legacy human biological material
- 65. Savings and transitional provisions
- 66. Related amendment to Health Products Act
- 67. Related amendment to Medicines Act
- 68. Related amendments to Mental Capacity Act
 - First Schedule Human biological material excluded from definition of human tissue
 - Second Schedule Research, studies and matters excluded from definition of human biomedical

research

Third Schedule — Prohibited human biomedical research Fourth Schedule — Restricted human biomedical research

Fifth Schedule — Waiver of requirements for appropriate consent by institutional review board