

CONTENTS

EXECUTIVE SUMMARY	1
PART A: INTRODUCTION AND CURRENT FRAMEWORK	
SECTION I. Introduction	
About these Guidelines	7
Objectives	8
SECTION II. The Current Framework	
The Background	9
Pharmaceutical Trials in Singapore	10
Human Biomedical Research other than Pharmaceutical Trials	12
PART B: HUMAN BIOMEDICAL RESEARCH	
SECTION III. Human Biomedical Research	
Defining Human Biomedical Research	16
Ethics Review of Direct Human Biomedical Research	18
Ethics Review of Indirect Human Biomedical Research	18
Exempted Review and Expedited Review of Human Biomedical Research	18
Stem Cell Lines	21
Cadaveric, Foetal and Legacy Tissues	21
Therapy versus Research	21
Legal Considerations	22
Savings	22
Exceptional Situations	22

PART C: ETHICS GOVERNANCE

SECTION IV. Principles of Ethics Governance

The Purpose of Ethics Governance	24
Applicable Principles	24

SECTION V. Institutional Review Boards

The Role of Institutional Review Boards	28
Shared and Domain Institutional Review Boards	30
The Responsibilities of Institutional Review Boards	31
The Constitution of Institutional Review Boards	33
Composition	34
Institutional Conflicts of Interest	35
Multinational and Multi-Centre Research Projects	36
Specific Operating Procedures for Institutional Review Boards	38

SECTION VI. Researchers

The General Responsibilities of Researchers	42
Principal Investigators	44
Continuing Responsibilities, Deviation and Variation	46
Researchers and Attending Physicians	47

SECTION VII. Institutions

The Responsibilities of Appointing Institutions	51
The Protection of Institutional Review Boards	53

SECTION VIII. Accreditation

The Accreditation of Institutional Review Boards	55
--	----

ANNEXES

Annexe A:	The Human Genetics Subcommittee	A-57
Annexe B:	Consultation Paper entitled “Advancing the Framework of Ethics Governance for Human Research”	B-58
Annexe C:	Distribution List	C-109
Annexe D:	Responses to the Consultation Paper	D-111
Annexe E:	Summary of the Dialogue Session	E-151
Annexe F:	Select References	F-157
Annexe G:	List of Abbreviations	G-159