

## Contents

	<i>Foreword by Professor Sir David Weatherall</i>	xi
	<i>Acknowledgements</i>	xiii
<b>1</b>	<b>An introduction to the ethical issues</b>	1
	Introduction	1
	What is the value of research?	3
	What are the limitations of research?	5
	What is the right way to treat human research participants?	6
	How can research participants' views be respected?	8
	Three areas of ethical concern in research: science, best interests and autonomy	9
<b>2</b>	<b>Goal-based morality: scientific rigour in research</b>	13
	The foundations of goal-based thinking	13
	Research should maximize health and minimize harm	13
	Utilitarianism's strengths and weaknesses	13
	Goal-based moral thinking applied to medical research	17
	The application of goal-based thinking	18
	The goals of research	18
	Methods of research	21
	Disseminating the results of research	25
	Summary and concluding remarks	30
<b>3</b>	<b>Duty-based morality: acting in the research subjects' best interests</b>	31
	The foundations of duty-based thinking	31
	From goals to duties	31
	Natural law ethics	32
	Kant's categorical imperative	34
	Duty-based moral thinking applied to medical research	36

**viii Contents**

---

	The application of duty-based thinking	39
	Therapeutic research	39
	Non-therapeutic research	43
	Summary and concluding remarks	45
<b>4</b>	<b>Right-based morality: respecting the autonomy of research participants</b>	47
	The foundations of right-based thinking	47
	From duties to rights	47
	Definitions of rights	48
	The validity of rights	53
	The applications of right-based thinking	57
	The consent procedure	57
	Concluding remarks on consent	61
	Confidentiality	61
	Summary and concluding remarks	63
<b>5</b>	<b>From principles to practice</b>	65
	Introduction	65
	Goal-based morality	65
	Goal-based morality's theoretical basis summarized	65
	Goals of research in theory and practice	66
	Research method summarized	67
	The practical implications of the choice of research method	67
	Summary of the problems with disseminating the results of research	67
	Introduction to practical examples of dissemination problems	68
	Duty-based morality	68
	Duty-based morality's theoretical basis summarized	68
	The practical implications of duty-based morality	69
	Introduction to examples	69
	Right-based morality	71
	Right-based morality's theoretical basis summarized	71
	Introduction to examples	71
	Does the three-approaches framework succeed?	72
<b>6</b>	<b>Case studies of goal-based issues</b>	73
	Introduction	73
	Goals of research	73
	Organ transplantation	73

	Contents	ix
Maintaining the condition of donor organs	75	
Xenotransplantation	77	
Autografting using cloned embryos	79	
Methods of research	80	
The discovery of penicillin was due to luck and hard work, but not planning	81	
Alternative and complementary therapy research needs open minds	85	
Trials in homeopathy	86	
Dissemination of the results of research	88	
Results of research into futile treatment depend on what is understood by 'futile'	88	
Results of pharmaceutical company research are always commercially favourable	89	
Results should ultimately meet public need	90	
Summary and concluding remarks	90	
 <b>7 Case studies of duty-based issues</b>	 93	
Introduction	93	
Therapeutic research	94	
Duty to care versus scientific goals: placebo controls in therapeutic research	94	
Trials of folic acid in pregnancy	95	
Trials for treatments of peptic ulcer disease	96	
Scientific arguments against the use of placebo	97	
The FDA's arguments for requiring placebo	98	
Meta-analysis of trials of ondansetron	100	
Concluding remarks	102	
Non-therapeutic research	103	
Duty to care versus scientific goals: potential risks in non-therapeutic research	103	
Duty to care versus patient autonomy: non-therapeutic healthy volunteer research indicates the need to protect subjects from harm even if they consent	106	
Summary and concluding remarks	110	
 <b>8 Case studies of right-based issues</b>	 113	
Introduction	113	
Consent	113	
Right-based difficulties with consent: the empirical evidence	114	
Duty-based difficulties with consent	121	

**x Contents**

Goal-based difficulties with consent	123
Written consent	126
Concluding remarks	128
Confidentiality	130
Should records-based or epidemiological research take place if it compromises patient autonomy?	130
Concluding remarks	132
Summary and concluding remarks	132
<b>9 A framework for ethical review: researchers, research ethics committees, and moral responsibility</b>	133
Introduction	133
The three approaches combined	133
A framework to assist ethical review	135
Goal-based questions	135
Duty-based questions	136
Right-based questions	136
Resolving conflicts between the three approaches	136
Goal-based questions to set the context	136
Goal-based and duty-based moral imperatives in conflict	136
Goal-based and right-based	137
Duty-based and right-based	138
Goal-based and right-based again	139
When the three approaches fail	139
Research ethics committees	140
The Nuremberg Code	141
Pappworth's guinea pigs	141
Sir Austin Bradford-Hill and Mrs. Hodgson	142
The Medical Research Council, the World Medical Association and the Royal College of Physicians	143
The Ministry of Health	143
The growth of research ethics committees' power	143
Multi-centre research ethics committees	144
'Who guards the guardians?'	145
Bradford-Hill's prophecy	145
Conclusion	146
<i>References</i>	147
<i>Index</i>	155