Contents

Table of Cases		ix
	nowledgements	xv
		1
Intro	oduction The Coverable of Extermally, Spangared Degearch in	1
	The Growth of Externally-Sponsored Research in	1
	Developing Countries Entermally Spangaged Degraph of Foreign Direct Investment:	1
	Externally-Sponsored Research as Foreign Direct Investment:	5
	The Indian Example Consequent About Example itations Ethical and Statutoms Doculation	8
	Concerns About Exploitation: Ethical and Statutory Regulation	200
	Issues of Legal Liability and African Law	18
	Summary of Chapters	24
1	Regulatory Contexts of Biomedical Research in Developing	
1	Countries	27
	Introduction	27
	International Regulatory Contexts	28
	Frameworks of Response to International Research Scandals	34
-	Impetus for the Regulation of Biomedical Research in Africa	37
	Regulatory Models in Africa	49
T.	Scope of Research Guidelines in Africa	55
	Enforceability of Guidelines in Africa	56
	Conclusion	57
2	Equipoise and the Normative Framework for Biomedical Research	
	in Africa	59
	Introduction	59
	Theoretical Equipoise	60
	Clinical Equipoise	64
	Which Way Africa? Clinical Equipoise or the Uncertainty Principle?	70
	Equipoise and the Duty to Provide the Best Treatment	74
	Equipoise and Placebo-Controlled Randomized Trials	79
	Equipoise and the Consent of Research Subjects	83
	Conclusion	87
3	Case Studies of Research Governance in Africa	89
	Introduction	89
	Uganda	91
	Tanzania	105

	Nigeria	111
	Conclusion	120
4	The Machinery of Ethics Review: Nature, Functions and Scope	123
	Introduction	123
	Functions of Research Ethics Committees	124
	Review of International Collaborative Research	145
	Bioethical Capacity Building and Training of Members of Ethics	
	Committees in Africa	153
	Funding of Ethics Committees and the Charging of Fees for Ethics	15/
	Review	156
	Commercial Ethics Review Committees	158
	Conclusion	163
5	Legal Liability of Research Ethics Committees in Actions by	
	Research Subjects	165
	Introduction	165
	Legal Personality of Research Ethics Committees	167
	Liability of Individual Members of Research Ethics Committees	170
	Negligent Acts and Omissions of Research Ethics Committees	174
	Recent Cases in Negligence against Research Ethics Committees	177
	Duty of Care	181
	Standard of Care and Breach of Duty	189
	Causation	190
	Liability to Professional Discipline	192
	Conclusion	195
6	Liability of Research Ethics Committees in Actions by Investigators	197
	Introduction	197
	Judicial Control and Review of Decisions of Research Ethics	
	Committees	198
	Grounds of Review	205
	Injunctions	208
	Procuring the Breach of a Research Contract	211
	Causing Loss by Unlawful Means or Unlawful Interference with	216
	Economic Interests	215
	Negligent Economic Loss	216
	Defamation	219
	Libel and Slander Defences to a Defenction Suit	221
	Defences to a Defamation Suit	223
	Right to Research Conclusion	221
	Conclusion	23]

Contents

7	Legal Liability of Investigators in Actions by Research Subjects	233
	Introduction	233
	Actions in Negligence	233
	Investigator-Research Subject Duty of Care	239
	Battery	243
	Constitutional Claims	247
	Right to Life	249
	Right to Human Dignity: Against Torture, Inhuman and Degrading	
	Treatment	253
	Unjust Enrichment	256
	Breach of Confidence	262
	Foreign Suits by African Research Subjects: Procedural and	
	Substantive Problems	266
	USA	269
	England and Wales	272
	Conclusion	274
Concl	lusion – Themes, Suggestions and Ruminations	277
	Research Involving Human Subjects in Africa: the Need for both	
	Ethical and Legal Analyses	277
	African Charter on Human and Peoples' Rights – Protocol on	
4	Research Involving Human Subjects and Embedment of Equipoise	278
	Establishment of a Clinical Trials Registry in African Countries	282
	Legal Liability: the 'Judicialization' of Research Involving Human	
	Subjects	285
	Value of Extraterritorial Litigation	286
Biblio	graphy	287
Index		311