

# **MONOGRAPH**

## **VOLUME - I**



**THE INSTITUTE OF LAW AND ETHICS IN MEDICINE**

**NATIONAL LAW SCHOOL OF INDIA UNIVERSITY**

**NAGARBHAVI, BANGALORE - 560 242.**

**MONOGRAPH - I**  
**UNBORN AND THE LAW**  
**CONTENTS**

Life and the Right thereto	13
The Human Foetus and the Right to Life	15
I    Who are the unborn?	15
II   The Right to Life of Unborn Persons	16
The primary issue-Legal Status	18
When and how can the foetus enforce its right to life?	33
Wrongful Birth and Wrongful Life	36
A few final words on Wrongful Life	42
Pre-Natal Diagnosis and Genetic Counselling	43
The Duty of the Doctor to Disclose Information	49
Interface - The Parental Right to Privacy and Bodily Autonomy	51
The Abortion Issue	54
The Abortion Interface	56
Knowledge, Duty and Standard of Care	57
Conclusion - An Issue-wise summary of findings	59

**MONOGRAPH - II**  
**TRANSSEXUALL AND THE LAW**  
**CONTENTS**

Introduction	67
Transsexualism-ideology and Legal Policy	69
Ideological Positions	69
Interest Groups within the State and their Approach.	70
The Medical Aspects of Transsexualism	72
Etiology	72
The Physician's Role	73
Legal Requirements for Surgery	74
Legal Implications of Sex Reassignment	77
Legality of Surgery for Sex Assignment	79
Civil Status and Rights of Post Operative Transsexuals	80
Transsexuals and the Validity of Marriage	84
Custodial Rights and Sex Reassignment	87
Discrimination and Sex Reassignment	87
The Implication of Sex Reassignment Surgery on Criminal Law	89
An American Perspective on Transgender Health Law	92
Conclusion	96
Bibliography	100

**MONOGRAPH III**

**ABORTION - SOCIAL, ETHICAL AND LEGAL ISSUES**

**CONTENTS**

Introduction	105
The medical profession	106
Various facets of the problem	106
The factual and the normative aspects	107
The normative aspects	107
Inter-relationship of various facets	109
When the child comes into existence?	111
When does the Law recognise the Child's existence?	112
Rights of the Mother vs. Interest of the Foetus	117
Consent of the Father	119
Wrongful Life & Wrongful Birth	120
Rights of the Mother	121
Conclusion	124
Principal issues for consideration	126
Bibliography	128
Appendix	131
A. The Medical Termination of Pregnancy Act, 1971	
B. The Medical Termination of Pregnancy Rules, 1975	
C. The Medical Termination of Pregnancy Regulations, 1 975	

**MONOGRAPH IV**  
**AUTOPSY AND THE LAW**  
**CONTENTS**

Introduction	155
Historical Development	157
The Coroner System	161
Issues Involved	163
The Ethical Issue	163
Medical Issue	163
Purpose	164
How the Post Mortem Examination is Conducted	166
Identity and Time	170
Odontology	175
Identification	178
Nature and Cause	179
Mechanical Injuries	180
Types of Wounds	189
Classification of Injuries	192
Firearm Injuries	197
Poisoning	198
Difficulties Faced by a Medical Practitioner	198
Legal Issues	199
Evidentiary Value under the Indian Evidence Act, 1872	201
The Workmen's Compensation Act	204
Accidental Deaths outside IPC	204
Other Deaths	205
Negligence of Medical Practitioner	205
Conclusion	206
Bibiliography	207
Appendix	208

**MONOGRAPH V**  
**HIV / AIDS TESTING : IN SEARCH OF POLICY**  
**CONTENTS**

Table of Cases	237
Introduction	239
HIV / AIDS : How is it caused and detected ?	241
The Human Immunodeficiency Virus:	241
Characteristics of HIV	241
Testing for HIV / AIDS	243
Test to Detect HIV Infection	243
Testing for HIV / AIDS : Approaches	244
Mandatory Testing	245
Paternalism	246
Utilitarianism	246
Voluntary Testing	253
Conclusion	260
Bibliography	262
Appendix	
1.    NACO Policy for HIV Testing	264
2.    Relevant Portion of International Human Rights Obligations and HIV / AIDS	269
3.    HIV Testing Request Form	275

**MONOGRAPH VI**  
**CLINICAL TRIALS - ETHICAL AND LEGAL ISSUES**

**CONTENTS**

Introduction	281
Understanding Clinical Trials	284
Pre-Clinical Testing and Studies	287
Pharmacodynamics	288
Pharmacokinetics	288
Pre-Clinical Toxicology	289
Extrapolation of Results	290
Early Studies in Man	291
Controlled Trials	291
Post-Registration Surveillance	296
The Phases in a Controlled Clinical Trial	296
Phase One Trials	296
Phase Two Trials	297
Phase Three Trials	297
Phase Four Trials	298
Special Procedures	298
Efficient, Ethical Clinical Trials	299
The Regulatory Regime for Clinical Trials	303
Basic Legal Principles and Issues in Clinical Trials of New Drugs	305
Informed Consent	305
Issues Raised	308

Response

Is there a need for Placebo-Controlled Trials ?

Vulnerable Population

Feminist Concerns

Assessment of Risks and Benefits

Confidentiality

Remuneration and Compensation for Injuries

Externally Sponsored Research

Conclusion

Bibliography

Annex I - Declaration of Helsinki

Annex II - The Belmont Report (Summary)

Annex III - Essential Information to be contained in  
an Informed Consent Form