

BHARATHIAR UNIVERSITY: COIMBATORE-641 046

CENTRE FOR COLLABORATION OF INDUSTRY AND INSTITUTION(CCII)
POST GRADUATE DIPLOMA IN BIOETHICS

(For the CCII students admitted from the academic year 2016-17 onwards)

Course Duration: One year

SCHEME OF EXAMINATIONS

PAPER	Course Title	University Examinations			
		Dur/Hrs.	Int.	Ext.	Total Marks
SEMESTER I					
I	Principles of Bioethics	3hrs	25	75	100
II	Bioethics and Law	3hrs	25	75	100
III	Basics of Research Ethics	3hrs	25	75	100
IV	Practical I – Basics of Bioethics	3hrs	40	60	100
SEMESTER II					
V	Advanced Research Ethics	3hrs	25	75	100
VI	Clinical and Public Health Ethics	3hrs	25	75	100
VII	Practical-II-Applied Bioethics	3hrs	40	60	100
VIII	Project*	--	--	--	100
	TOTAL				800

*** for Project report - 80 marks; Viva-voce – 20 marks**

Paper I: PRINCIPLES OF BIOETHICS

Aim

1. Explain the Significance of Bioethics and the history and evolution of bioethics and various ethical guidelines.
2. Discuss the relationship between philosophy and bioethics and the various theories in Indian and Western philosophy.
3. Describe the ethical approaches and theories in various religions.

UNIT I

Introduction to Bioethics

What is Bioethics, Significance of Bioethics

UNIT II

History of Bioethics

Evolution of Bioethics-important timelines, Tuskegee syphilis experiments, Nuremberg trials, Willowbrook experiments

UNIT III

Codes and guidelines

Belmont Report- Principles of Bioethics and Application, Nuremberg code, CIOMS guidelines, Guatemala Trials, Indian codes of Ethics, ICMR Ethical Guidelines –General and Specific Principles, Indian Medical Council Act, Schedule Y, Indian GCP, Clinical Trial Registry of India, Ranjith Roy Choudhry report-Salient features

UNIT IV

Bioethics and Philosophy

Introduction to Philosophy, Guidelines and Law ,Indian Philosophy-Historic division of Indian Philosophy, Different Schools of Philosophy –The Purusharthas –Sadharana Dharma and Vishesh Dharma

Western Philosophy-Ethical Theories, Development of Ethics, Consequentialism, Deontology, Value ethics, Virtue Ethics, Feminist Ethics, Ethics of Care

UNIT V

Bioethics and Religion

Morals and Ethics –Definition, Fundamental Religious beliefs, Sanadhana Dharma, four goals of human life, Hindu approach-concept of Dharma and Karma, Christian Ethical Sources-Old and New testament, ten commandments, Diversity in Christian Ethics- Catholic, Protestant and Eastern orthodox ethics. Islamic Ethics- Four sources, Sunni Vs Shia jurisprudence, Judaism, Religion and Stem cell research

References:

1. Beauchamp TL, Childress JF [2011]. Principles of Biomedical Ethics. Edition 5. Oxford University Press, New York.
2. Timms O [2016]. Biomedical Ethics. Edition 1. Elsevier
3. Ethical Guidelines for Biomedical Research on Human Research, ICMR, 2006
4. International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, 2002
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[http://www.cdsco.nic.in/writereaddata/Report_of_Dr_Ranjit_Roy.pdf]
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Paper II : BIOETHICS & LAW

Aim

1. Understand the basic principles of law and its relationship with bioethics
2. Describe the Legal framework in the Indian judicial system
3. Discuss the various sources of Indian law and how to read a legal opinion
4. Understand the laws related to health care

UNIT I

Introduction to Bioethics and Law

Bioethics Principles in relation to law, Similarities and Differences between Bioethics and Law

UNIT II

Indian Judicial System

Supreme courts, High Courts, Subordinate courts

UNIT III

Sources of Indian Law

Legislation- Bills, Sources of Legislative information, Case Law and Other sources including Digests, Halsbury's laws of India, Legal textbooks and Law commission reports, Public health law in India-Framework and Indicators, Reading a legal opinion

UNIT IV

Society and Legal System

Justice different system of Justice-Distributive, Procedural, Restorative and Retributive Justice

UNIT V

Doctors and Law

Clinical Ethics, Law and Risk management –Conceptual models, Potential legal actions against health care providers

References

1. Beauchamp TL, Childress JF [2011]. Principles of Biomedical Ethics. Edition 5. Oxford University Press, New York.
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8. Global Network of WHO collaborating centers for Bioethics. Global Health Ethics – Key Issues. Introduction to health ethics: key concepts. Page 10 - 11
9. University of Washington School of Medicine. Ethics in medicine. Clinical Ethics and Law.<https://depts.washington.edu/bioethx/topics/law.html>-page no-1 -8
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Paper III : BASICS OF RESEARCH ETHICS

Aim

1. Describe the basic principles of research
2. Discuss the different study designs and the advantages and disadvantages of each
3. Know the basic concepts of biostatistics
4. Describe the concept of Responsible Conduct of Research and ethical issues involved in Publication

UNIT I

Introduction to Research

Concepts and types of research-basics of research methodology, Quantitative and Qualitative Research

UNIT II

Research protocol and Study designs

Study designs, Observational and Experimental designs, Cross sectional studies , Cohort studies, Case control studies , RCTs, Advantages and Disadvantages of each design

UNIT III

Basics of Biostatistics

Mean, Median, Mode, Variables, Tests of significance, Non parametric tests, Sampling and Sample size in Research

UNIT IV

Responsible Conduct of Research

Responsible Conduct of Research (RCR)- Important elements

UNIT V

Publication Ethics

Authorship- ICMJE guidelines, Addressing Conflicts of Interest, Preserving Confidentiality of patients, Definition-Redundant publication, Salami slicing, COPE- Guidelines, Plagiarism – Definition – Etymology - Detecting Plagiarism, Predatory journals , Dealing with Research misconduct

References

1. Beauchamp TL, Childress JF [2011]. Principles of Biomedical Ethics. Edition 5. Oxford
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4. Ethical Guidelines for Biomedical Research on Human Research, ICMR, 2006
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10. Designing clinical Research: Stephen Hulley: Fourth Edition
11. Committee on Publication Ethics(COPE) <http://publicationethics.org>

Paper IV : ADVANCED RESEARCH ETHICS

Aim

- 1 .Discuss basic concepts of research ethics including informed consent process, justice and vulnerability in research
2. Know the composition, roles and responsibilities of Human ethics committees
3. Describe the different types of review mechanisms and risk benefit analysis
4. Enlist the various phases of clinical trial and
5. Describe the recent clinical trial regulations
6. Discuss the ethical issues involved in animal experimentation and the various law related to it.

UNIT I

Basic Concepts of Research Ethics

Informed consent –Key elements, Contents of Informed consent, Requirement and Process of Informed Consent, Special issues- Consent for use of Biological material, Consent in Emergency situations Waiver of Consent , Assent, Major issues related to informed consent in India, Multimedia approach in Consent, Vulnerability in Research : Concepts, Informed consent and Vulnerability, Types of Vulnerability Historical perspectives, Problems with Vulnerability, Economic Vulnerability. ICMR and CIOMS guidelines, Belmont report and US Federal regulations –definition of vulnerability

UNIT II

Institution Human Ethics Committee

Composition of Human Ethics Committee, Membership, Roles and Responsibilities of each member, Review Process- Exempt, Expedited and Full board Review, Confidentiality,

Conflict of interest, Coercion and Inducement, Risk Benefit Analysis in the Review process. Documentation process in Ethics Committees. Accreditation of Ethics Committees

UNIT III

Introduction to Clinical Trials and Recent regulatory guidelines

Phases of clinical trials, Indian GCP, Schedule Y, Recent regulatory changes including compensation, Audio Video consent, Clinical trials of drugs, devices and herbal products and their regulatory guidelines. Regulations related to Surrogacy, Organ transplantation. Clinical Establishment Act, Drugs and Cosmetics Act and amendments, SAE in clinical trial and SAE Reporting

UNIT IV

Ethical Issues in Animal Experimentation

Purpose of using Animals in Experimentation, Importance of using Animals in Biomedical Research, Benefits and important discoveries using Animals in Research, Major concerns in Animal Experimentation, Legislation in Animal Experimentation, Three “R” s in animal experimentation, Indian Guidelines in Animal Experimentation, INSA, ICMR and CPCSEA Guidelines ,International Guidelines, Institutional Animal Ethics Committees

UNIT V

Recent advances and Special Topics

Genetics –Ethical issues in genetic testing, Informed Consent, Assisted Reproductive Technology, Stem cell Research, Data and Ethics, Ethical issues in Bio banking, Ethical of Social Science Research

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1. Beauchamp TL, Childress JF [2011]. Principles of Biomedical Ethics. Edition 5. Oxford University Press, New York
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Paper V: CLINICAL AND PUBLIC HEALTH ETHICS

Aim

1. Discuss the significance of doctor patient relationship
2. Describe clinical code of conduct, medical negligence, medical error, confidentiality and privacy
3. Apply theories, principles and framework in addressing ethical issues in clinical practice
4. Describe the concepts of public health ethics
5. Apply methods, principles and framework in addressing ethical issues in public health

UNIT I

Introduction to Clinical Ethics

Doctor Patient Relationship, Communication skills, Breaking bad news, Clinical code of conduct, MCI Code of ethics, Hippocrates Oath

UNIT II

Medical errors and Negligence

Medical Error, Medical Negligence, Irrational Drug use, Conflicts in Clinical Ethics, Patient confidentiality and Privacy, Principle of Non Maleficence Vs Other Principles, Clinical Establishment Act

UNIT III

Methods and Special topics in Clinical Ethics – Four box method, Beginning of life decisions, End of life decisions, Euthanasia –Types and Indian Law on Euthanasia, Divergent Case method, General medical Vs Ethical Consultation, Surrogate decision making, Ethical issues in organ transplantation

UNIT IV

Introduction to Public Health Ethics

Evolution and current discourse, areas in Public Health with ethical issues, Overarching principles and Values in Public Health Ethics, Balancing interests of individuals Vs larger public

UNIT V

Methods and Special topics in Public Health Ethics

Elements of decision making in Public Health, Approaching ethical issues in Public Health, Contribution of Ethics to Public Health, Gender issues in Public Health, Human Rights and Public Health Ethics, Feminism and Public Health Ethics

References:

1. Beauchamp TL, Childress JF [2011]. Principles of Biomedical Ethics. Edition 5. Oxford University Press, New York
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Practical I

Evaluation based on

1. Viva and
2. Case studies

Practical 2 Evaluation based on

1. Viva
2. Case studies
3. Project related viva

Paper VIII: Project

All students will complete a short project related to Bioethics. The projects can be original research both quantitative and qualitative research or review articles on topics related to bioethics.

Internal Assessment will be from

1. Assignments completed during the course
2. Discussions- online and onsite
3. Journal Review
4. Movie Critique
5. Book Review
6. Seminars