

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 2014-15 and onwards)

Duration: One year (Two Semesters)

SCHEME OF EXAMINATIONS

PAPER	Course Title	Dur. Hrs.	Total Marks
	SEMESTER –I		
I	Philosophy and Religion in Ethics	3	100
II	Principles of Bioethics	3	100
III	Bioethics and Law	3	100
IV	Research Methodology & Communication Skills	3	100
V	Practicals I – Basics of Bioethics	3	100
	SEMESTER –II		
VI	Research Ethics	3	100
VII	Recent Advances and Ethics	3	100
VIII	Publication Ethics	3	100
IX	Ethics and Regulations	3	100
X	Practical's-II-Applied Bioethics	3	100
	TOTAL		1000

SEMESTER –I

PAPER I- Philosophy and Religion in Ethics

Aim: At the end of this session, the student would be able

1. To understand the connection between philosophy and ethics
2. Become familiar with the religious viewpoints in ethics

UNIT I: Introduction to Philosophy

Introduction-Definition - Basics of Philosophy -Various systems in Philosophy-Issues in Philosophy

UNIT II: Various systems in Philosophy

Objectives –Introduction-Indian and western philosophy- comparison of the two systems of philosophy

UNIT III: Indian Philosophy

Introduction-Nature of Indian Philosophy- Issues In Indian Philosophy- Philosophical Systems-Goals in Life (Purushartha) -Ethical Principles in Recognized Indian Traditional Systems of Medicine

UNIT IV: Philosophy and ethical issues

Dharma and other Moral Concepts - Issues Concerning Good and Healthy Life - Emphasis on this life - Emphasis on life after death and eternal life - Emphasis on both - This life and the next.

UNIT V: Western Philosophy

Introduction to Classical Theories of Morality-Virtue ethics- deontological concepts- Utilitarianism-Utilitarian principle of Moral Action

Reference Material

1. ICMR Ethical Guidelines for Biomedical Research (2006)
2. The Four Principles of Biomedical Ethics: A Foundation for Current Bioethical Debate (Dana J. Lawrence, DC, MMedEd)
3. Principles of Bioethics (Thomas R. McCormick, D.Min., Senior Lecturer Emeritus, Dept. Bioethics and Humanities, School of Medicine, University of Washington)
4. Religious perspectives of human vulnerability and bioethics edited by Tham, Joseph, Garcia, Alberto, Miranda, Gonzalo 2014.

PAPER II- Principles of Bioethics

Aim: At the end of this session

- To enable the students to learn principles, covenants, declaration and guidelines in Bioethics

UNIT I: History of Bioethics

Introduction - Meaning of the term "Bioethics" - Historical Evolution of "Bioethics" - Biomedical Research Ethics-Universal Principles of Bioethics.

UNIT II: Codes covenants

Introduction - Medical Profession and Biomedicine – differentiation of Prayers, Oaths, covenant- Declarations –Codes Related to Bioethics

UNIT III: Declaration

The Declaration of Geneva- Universal Declaration on Bioethics and Human Rights

UNIT IV: Guidelines in Bioethics

Definition-Codes of Bioethics - guidelines in Bioethics

UNIT V: Universal Principles of Bioethics

Universal Principles of Bioethics-Principles in relation to research and clinical practice

Reference Materials

1. Nigel M, Cameroon DS. Life and Death after Hippocrates: The New Medicine. Wheaton IL, Ed. Crossway Books, 1991: 23-45.
2. Veatch RM. A Theory of Medical Ethics. New York, Basic Books, 1991: 125-6.
3. Cassel CK. The patient-physician covenant: An affirmation of Asklepios. Ann Intern Med 1996; 124: 604-6.
4. Steinbrook R. Controlling conflict of interest-proposals from the institute of medicine. New Engl J Med 2009; 360: 2160-3.
5. Jagsi R, Tarbell NJ, Weinstein DS. Becoming a doctor, starting a family- Leaves of absence from graduate medical education. New Engl J Med 2007, 357: 1889-91.
6. Allen J. Love and conflict: A Covenantal Model of Christian ethics. Nashville, TN: Abdingdon Press, 1984.
7. Rusthoven JJ. Understanding Medical relationships through a covenantal ethical perspective. Perspective Science Christian Faith; 62:3-15.
8. Beauchamp TL, Childress JF. Principles of Biomedical Ethics, 6th Edn. Oxford, Oxford University Press, 2001: 397-408.
9. Veatch R. Medical codes and oaths. In: Encyclopedia of Bioethics, 2nd Edn. New York, Simon & Schuster Macmillan, 1995: 1419-35.

PAPER III Bioethics and Law

Aim: To bring awareness amongst students to Know about the difference between ethics and law

UNIT I: Introduction to Bioethics and law

Definition - Milestones in ethics and law, Comparison of Bioethics and law

UNIT II: Legal system in India

Objectives-Justice Law and Society: Introduction-Constitution of India-Legal Framework - Substantive and Procedural-Legal System

UNIT III : Legal governance and Ethics

Legal and Ethical Accountability - Premise and Extent Right to Health and Health Care - Judicial perspective

UNIT IV: Doctors and Law

Legal Accountability of Doctors- Doctor Patient Relationship - Ethical Accountability of Doctors - Ethics and Healthcare Professionals- Essential information about COPRA, Organ transplant acts and other health related acts

UNIT V: Society and Legal system

Introduction -Justice, Law and Society – Understand significance of Justice in the context of Law - Understand the legal system and pertinent legal principles.

Reference Materials

1. Legal aspects of death & dying
2. International convention :WHO edition
3. Compendium of articles related to Law and ethics
4. Harris John, (2003). Organ procurement: dead interests, living needs. J Med Ethics 2003; 29:130-134, Debate, Editorial.
5. Glannon Walter, (2009). Free riding and organ donation. J Med Ethics 2009; 35:590-59, Editorial.
6. Quigley M; Brazier M; Chadwick R; et al., (2008). The organs crisis and the Spanish model: theoretical versus pragmatic considerations. J Med Ethics 2008; 34:223–4.
7. Nadir Nupur, (2008). Law and Medicine: An Analysis of The Organ Transplantation Law in India. Organ Transplantation Law In India, 9th June 2008;<http://www.legalserviceindia.com/article/1224-Organ-Transplantation-Law-In-India.html>.

PAPER IV Research Methodology & Communication Skills

Aim:

1. Comprehend the basics of research methodology including study designs and basics of biostatistics
2. Understand the significance of communication skills especially in health care

UNIT I: Introduction to Research Methodology

Introduction-Concepts in research- types of research- basics of research methodology
Quantitative Research Methods, Qualitative Research methods

UNIT II: Elements of a research protocol and Study designs

Introduction -writing SMART objectives- Methodology - Types of study designs -
Advantages – Disadvantages- Ethical issues in sampling, how to calculate sample size-

UNIT III: Quantitative Research Methods, Qualitative Research methods

Introduction, Basics, Epidemiology, Causal associations and measures of disease frequency,
Diagnostic and screening tests-Clinical trialsQualitative Research Analysis

UNIT IV: Basics of Biostatistics

Introduction to Biostatistics - Descriptive statistics- Tests of significance -Strength of
association -Sampling and sample size Estimation-Inferential statistics-Correlation

UNIT V : Communication skills

Importance of Communication Skills, Presentation skills, writing a paper, making a
PowerPoint, Doctor- Patient Communication.

Reference Materials

1. Designing Clinical Research :Stephen Hulley 4th Edition
 2. Basic Epidemiology : WHO 2nd edition : R Bonita R Beaglehole, T Kjellstrom
- In addition, a compendium of interesting articles will be provided to each candidate as part of reading material.

PAPER V –Practicals-I -Basics of Bioethics

Aim: Upon completion of this course will emphasize the students to get the Practical knowledge this will help them doing the further research.

1. Viva as an evaluation tool
2. Assessment based on
3. Assignments
4. Case studies
5. Discussions
6. Journal Review
7. Movie Critique
8. Seminars

SEMESTER –II**PAPER VI- Research Ethics**

Aim: At the end of this course, the student will be able to

1. Understand the ethical principles in animal experimentation
2. Relate the ethical principles in social sciences research

UNIT I: Ethics committees and functioning-Constitution, selection of members, roles of each member- Review process - Informed consent –Animal & Human Research

UNIT II: Social Science Research- Ethical issues involved in Social sciences research -Types of review - expedited, exempt and full board review

UNIT III: Recent regulations in clinical trial - Newer guidelines on notification - compensation issues in clinical trial

UNIT IV: Ethical issues in epidemiological studies - Ethics of observational studies - informed consent issues in population based studies-Epidemiology Genetics

UNIT V: All health related acts - guidelines –Clinical and public health ethics Organ transplantation Act

Reference Materials

1. Indian Council of Medical Research (ICMR). Statement of the general principles in biomedical research involving human participants. Ethical Guidelines for Biomedical Research on Human Participants, 2006: pp 3-7
2. A. Jesani & T. Barai – Jaitly (Eds). Ethics in health research: A social science perspective. Mumbai: Centre for Studies in Ethics and Rights; 2005.
3. ICMR. Ethical guidelines for biomedical research on human participants. New Delhi: Indian Council of Medical Research; 2006.
4. ICMR. Contemporary ethical issues in biomedical and health research. New Delhi: Indian Council of Medical Research; 2007.
5. K. S. Agarwal & R. Sripat. Medical Negligence: Role of Patient Consent in Operating Procedures. In KN Bhatt, S Misra & S Chadah (eds.) Consumers, consumerism and consumer protection – Indian Context. Delhi: Centre for Consumer Studies, Indian Institute of Public Administration. 2010.
6. NCESSRH. Ethical guidelines for social science research in health. National Committee for ethics in Social Science Research in Health. 2000. www.cehat.org/publications/ethical1.html,
7. Verastegui,E.L. Consenting of the vulnerable; The informed consent procedure in advanced cancer patients in Mexico. BMC Med Ethics 2006; 7, 1-19.

PAPER VII- Recent Advances and Ethics

Aim: To enable the students

1. To learn the recent advances in Bioethics.
2. To learn the ethical issues involved in genetics and stem cell research
3. to learn various aspects of Ethical Implications

UNIT I: Ethical Issues with genetic engineering research-Ethical Issues In Assisted Reproduction - Ethics of Art - Future issues

UNIT II: Introduction - Reproduction as a Fundamental Right - Artificial Reproduction Technologies and Ethics – The orphan embryo in Assisted reproductive technologies

UNIT III : Guidelines for stem cell research - Statement of Specific Principles for Human Genetics and Genomics Research -Defining risks and benefits -principles governing research in human genetics – informed consent in genetic research, ethical issues in genetic testing

UNIT IV: Rules and regulations in every country where ethical concerns were raised regarding human Genetics- International Laws on Stem Cell Research and Therapy

UNIT V: Advances in sciences & technology and the ethical issues-New technologies- Genetic Engineering-Synthetic Biology-

Reference Materials

1. N Pandiyan. Embryo sex selection: a social comment on the article by Malpani and Malpani; Reproductive BioMedicine Online Vol. 4, Issue 1, 2002,Pages 9-10
2. Indian Council of Medical Research. Ethical guidelines for bio-medical research on human participants; Chapter VII . New Delhi (2006);
3. Singer, Peter A and Viens A.M., (2008). The Cambridge Textbook of Bioethics. Cambridge University Press.

PAPER VIII- Publication Ethics

Aim: To enable the students

1. to learn Principles of Publication ethics, and plagiarism
2. to Understand the concepts of publication ethics

UNIT I: Introduction -Study design and ethical approval-Principles of Publication ethics - Guidelines - Data Analysis

UNIT II: Authorship- Definition -Conflicts of Interest -Preserving Confidentiality of patients- Manuscript submission- Peer review

UNIT III : Definition-Redundant publication –COPE- Guidelines

UNIT IV: Plagiarism – Definition – Etymology - Detecting Plagiarism - The Golden Rule - Dos and Don'ts of Plagiarism

UNIT V: Dealing with misconduct – Principles - Investigating misconduct - Serious misconduct - Less serious misconduct- Ethical Issues in cyber based research and E-Learning

Reference Materials

1. Committee on Publication Ethics. Guidelines on Good Publication Practice. Family Practice 2000;17:218-21.
2. International Committee of Medical Journal editors [Home page on Internet]. Last accessed on Jan11, 2011. Available from URL <http://www.icmje.org/>
3. COPE code of conduct. Available from <http://publicationethics.org/>
4. Albert T, Wager E. How to handle authorship disputes: A guide for new researchers. COPE Report 2003;1:32-4.
5. The PLoS Medicine Editors. PLoS Medicine's Advisory Group on Publication Ethics. PLoS Medicine 2007;4:e81.
6. Handa S. Plagiarism and publication ethics: Do's and Dont's. Indian J Dermatol Venerol Leprol 2008;74:301-4.

PAPER IX- Ethics and Regulations

Aim: To enable students to acquire knowledge in Regulations related to Ethics

UNIT I: Clinical establishment Act, 2010 -Regulations related to Clinical trials Phases of clinical trials -Prevention trial-Other non-treatment clinical trials-Sample size calculations

UNIT II : Randomization-Blinding and allocation concealment-Intention to treat and participant withdrawal-Alternatives to intention to treat-Endpoints-Subgroup and interim analysis -Trial monitoring

UNIT III : Organ Transplantation Act, 1994- Ethics of Transplantation - Transplants from Live, Cadaver,Deceased Donors - Permissible Areas of Research

UNIT IV: Regulations related to environmental protection related to health, Local self-governance & health related issues

UNIT V: Regulations related to food Intellectual Property Right, Regulations related to occupational hazards and safeguards, Compensation and Insurance issues

Reference Materials

1. Indian Council of Medical Research. Ethical guidelines for bio-medical research on human participants; Chapter VII . New Delhi (2006);
2. Harris John, (2003). Organ procurement: dead interests, living needs. J Med Ethics 2003; 29:130-134, Debate, Editorial.
3. Glannon Walter, (2009). Free riding and organ donation. J Med Ethics 2009; 35:590-59, Editorial.
4. Quigley M; Brazier M; Chadwick R; et al., (2008). The organs crisis and the Spanish model: theoretical versus pragmatic considerations. J Med Ethics 2008; 34:223–4.
5. Nadir Nupur, (2008). Law and Medicine: An Analysis of The Organ Transplantation Law in India. Organ Transplantation Law In India, 9th June 2008;<http://www.legalserviceindia.com/article/1224-Organ-Transplantation-Law-In-India.html>.
6. Singer, Peter A and Viens A.M., (2008). The Cambridge Textbook of Bioethics. Cambridge University Press.
7. Abadie, A.,M and Gay, S. (2006). The impact of presumed consent legislation on cadaveric organ donation: a cross country study. J Health Econ 25: 599-620.
8. Schmidt, V.H. and Lim, C.H. (2004). Organ transplantation in Singapore history, problems and policies. Soc Sci Med 59: 2173-82.
9. Bagheri, A. (2005). Organ transplantation laws in Asian countries: a comparative study. Transplant Proc 37: 4159-62.
10. Darr, A.S. (2004a). Money and organ procurement: narratives from the real world. In Ethical, Legal and Social Issues in Organ Transplantation, ed. T. Gutmann, A.S. Darr, R.A. Sells, and W. Land. Lengerich: Pabst Science, pp. 298-317.
11. MBBNet (2007). <http://mbbnet.umn.edu/scmap.html>.
12. http://en.wikipedia.org/wiki/Stem_cell_research_policy
13. Kaldjian, L. C., (2005). Are individuals diagnosed with brain death really dead? Law and Ethics, Vol. 5, No.1, January 2005.
14. Capron Morgan Alexander, (2001). Brain Death- Well Settled Yet Still Unresolved The New England Journal of Medicine, April 19, 2001, Vol. 344, No. 16.
15. Pathak Y V. Ingredients, Formulations and Applications In:Handbook of Nutraceuticals Vol 1. Boca Raton, New York. CRC Press 2010
16. Dyaneshwar Warude and Bhushan Patwardhan. In : Botanicals: Quality and Regulatory issues. Journal Of Scientific and Industrial Research Vol. 64; 2005:83-92

PAPER X –Practicals-II-Applied Bioethics

1. Viva as an evaluation tool
2. Assessment based on
3. Assignments
4. Case studies
5. Discussions
6. Journal Review
7. Movie Critique
8. Seminars