PG Diploma in Bioethics – 2014-15 onwards – CCII

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**

<table>
<thead>
<tr>
<th>PAPER</th>
<th>Course Title</th>
<th>Dur. Hrs</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEMESTER –I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Philosophy and Religion in Ethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>II</td>
<td>Principles of Bioethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>III</td>
<td>Bioethics and Law</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>IV</td>
<td>Research Methodology &amp; Communication Skills</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>V</td>
<td>Practicals I – Basics of Bioethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>SEMESTER –II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI</td>
<td>Research Ethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>VII</td>
<td>Recent Advances and Ethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>VIII</td>
<td>Publication Ethics</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>IX</td>
<td>Ethics and Regulations</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>X</td>
<td>Practical’s-II- Applied Bioethics</td>
<td>3</td>
<td>100</td>
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<td>TOTAL</td>
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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-Virute 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)
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

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
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

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
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 trials Qualitative 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

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
3. ICMR. Ethical guidelines for biomedical research on human participants. New Delhi: Indian Council of Medical Research; 2006.
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);

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

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);

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