II SEMESTER –BIOETHICS AND BIOSAFETY: BCS 456 SOFTCORE

Total Number of Lecture Hours: 42 **Total Number of Credits: 03**

Unit I **16 hrs.**

Introduction to Ethics -The moral point of view, The nature of moral judgements, An ethical method of reasoning, The birth of bioethics, Health and disease as values, Principles of bioethics, Ethics committees, Medical professionalism. **Human dignity and human rights** - Concepts of dignity in the history of ideas, Equality in dignity of all human beings, Respect and care, Ethical aspects of health care provider-patient relations in regard to human dignity and human rights. Benefit and harm - Autonomy and individual responsibility - Consent - Persons without the capacity to consent- Respect for human vulnerability and personal integrity- Privacy and confidentiality.

Unit II **16 hrs.**

Equality, justice and equity- Non-discrimination and non-stigmatization - Respect for cultural diversity and pluralism- Solidarity and cooperation- Social responsibility and health - Sharing of benefits -Protecting future generations- Protection of the environment, the biosphere and biodiversity. **Regulatory Procedures**: Good laboratory practice, Good manufacturing practice and FDA regulations - Regulations for recombinant DNA research and manufacturing process - Regulations for clinical trials, Documentation and Compliance, in India and selected countries - Rules for import and export of biological materials.

Unit III **10 hrs.**

Work planning and risk assessment -Biosafety containment levels - Personal Protective Equipment and clothing - Biosafety labels and signs - Facilities, equipment, and practices - Biological Spills and Decontamination, Biological waste disposal and pests - Transport and shipping - Emergency and incident response- Competency and responsibilities.

References:

1. The Bioethics Core Curriculum of UNESCO.
2. Raymond J. Devettere, Practical Decision Making in Health Care Ethics 2nd Edition. Washington, D.C.: Georgetown University Press, 2002. (ISBN 0-87840-763-4).
3. Weston, Anthony. A Rulebook for Arguments, 3rd Edition. Hackett, 2000. ISBN 0-87220-552-555.
4. Richmond JY, McKinney RW. Primary containment for biohazards: selection, installation and use of biological safety cabinets, 2nd ed. Washington, DC, United States Department of Health and Human Services/Centers for Disease Control and Prevention/National Institutes of Health, 2000.
5. Furr AK. CRC handbook of laboratory safety, 5th ed. Boca Raton, FL, CRC Press, 2000.
6. Springthorpe VS, Sattar SA. Chemical disinfection of virus-contaminated surfaces. CRC Critical Reviews in Environmental Control, 1990, 20:169–229.
7. Recommendations on the transport of dangerous goods, 13th revised edition, New York and Geneva, United Nations, 2003, (http://www.unece.org/trans/danger/publi/unrec/rev13/ 13files_e.html).
8. Technical instructions for the safe transport of dangerous goods by air, 2003–2004 Edition. Montreal, International Civil Aviation Organization, 2002.
9. Economic Commission for Europe Inland Transport Committee. Restructured ADR applicable as from 1 January 2003. New York and Geneva, United Nations, 2002, (http:// www.unece.org/trans/danger/publi/adr/adr2003/ContentsE.html).