



**MANGALORE UNIVERSITY**  
**DEPARTMENT OF BIOSCIENCES**  
**MSc BIOTECHNOLOGY**

**BTS 553**

**REGULATIONS AND INTELLECTUAL PROPERTY RIGHTS**

**Hours: 40**

**Course outcome**

The students will be able to learn:

- General guidelines and bio safety practices for recombinant DNA research
- Protection and registration of new plant varieties and plant germplasm conservation
- General agreement on trade and tariff, use of traditional knowledge digital library i.e ayurvedic and unani medicinal plants
- Farmers rights and plant breeders rights.

**UNIT I (13 hrs)**

Biosafety and research: General guidelines for recombinant DNA research activity. Containment facilities and biosafety practices; Rules for import and export of biological materials. Biological warfare and Bioterrorism.

**UNIT II (13 hrs)**

CBD, GAAT, TRIPs, Plant variety protection, International Union for the Protection of new Varieties of Plants (UPOV), plant protection act, registration of new varieties, rights and obligations, farmer's rights; traditional ecological knowledge. Traditional knowledge digital library (TKDL). Plant germplasm conservation, characterization and documentation. Seed certification (laws, regulations and standards), seed patent law.

**UNIT III (14hrs)**

Intellectual property rights (IPR) (meaning, classification and forms), importance of IPR in Science and Technology. Patents, patenting procedures, patent applications and patenting laws; Biopiracy. Patent-related litigations and controversies (neem, basmathi rice, turmeric). Salient features of Indian Patent Law.

**References**

1. Biotechnology, Biosafety and Biodiversity. Shantharam, S. & J.F. Montgomery. Science Pub., 1999
2. Biotechnology. Rehm H.-G. & G. Reed, Wiley Blackwell Pub., 1983
3. Biotechnology and the Law: IPR Vol.1 & 2. Cooper, I.P. Clark Boardman Co., 1989
4. Ethical guidelines for Biomedical Research on Human participants, Indian Council for Medical Research, Govt. of India, New Delhi, 2006
5. Good Clinical Practices for Clinical Research in India, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India, 2013