Course title: Bioethics, IPR and Regulations in Biotechnology			
Course code: BBP 149	**No. of credits:** 3	**L-T-P:** 39-6-0	**Learning hours:** 45
Pre-requisite course code and title (if any): None			
Department: Department of Biotechnology			
Course coordinator(s): Dr. Vidhi Madaan Chadda	**Course instructor(s):** Dr. Vidhi Madaan Chadda / Prof. K. P. Kochhar		
Contact details: vidhim.chadda@terisas.ac.in			
Course type: Core	**Course offered in:** Semester 3		

Course description:

Ethics encompass the guiding principles to prescribe what is fair and right. It includes components such as values, integrity, morality etc. Considering the impact of modern biology and medical research and its associated socio-economic importance, researchers need to be sensitive to the ethical obligations while designing and conducting research and disseminating research outcomes. On the other hand, the perceptions of the society about the scientific innovations are not uniform. Some consider the innovations as solutions; but there may have concerns as well.

The part A of the present course deals with the ethical issues related to biotechnology. It seeks to sensitize the candidates to wider issues concerning the ethics in biotechnology. The topics include ethics relating to transparency in scientific validation and ownership issues. Further, topics such as stem cell transplantation, xeno-transplantation and the impact of rDNA-based medicines on the public morality would be discussed. The importance of effective communication strategies is also covered.

The part B deals with the intellectual property rights and regulatory issues related to biotechnology. The course includes various regulations, national and international, and treaties related to biological processes, research and materials.

Course objectives:

1. Creating awareness among the students about ethics in research
2. Imparting knowledge about the relevant national laws and regulations related to biotechnological research and their products
3. Providing knowledge about different kinds of IPRs with especial reference to biotechnological research

Course contents

Module		L	T	P
	Part A: Bioethics	**10**		
1	**Overview of Bioethics and ethical issues in biotechnology** Socio-economic issues and broader impact on society Transparency and scientific validation on regulatory procedures Research priorities and ownership issues	5		
2	**Public Awareness and communication strategies** Bioethics involved in experimental animals and clinical research. Developing effective communication strategies Dissemination of scientific information effectively in common language	5		
	Part B: IPR and Regulations in Biotechnology	**29**	**6**	
3	**Principles and Perspectives on Biotechnology Regulation**	**7**		
	Introduction to legal framework Constitution, Statutes, Rules, Regulations, Judicial System, Administrative set up. International Law, Sources, Treaties Principles of Biotechnology Regulation: Risk Assessment, Risk Management and Risk Communication.			

	Precautionary principle and precautionary approach Country Comparisons on perspectives and approaches to Biotechnology Regulations The U.S. and E.U. approaches on Biotechnology research, Intentional introduction into environment, GM Food, labelling etc.			
4	**International framework for Biotechnology**	6		
	Multilateral Agreements: Convention on Biological Diversity, Cartagena Protocol on Biosafety, WTO Agreements, Codex Alimentarius, Plant Genetic Resources for Food and Agriculture. Judicial response to disputes on biotechnology trade and development			
5	**Regulatory Systems in India**	8	2	
	Environment Protection Act, 1986 Rules for the manufacture, use, import, export and storage of hazardous micro- organisms, genetically engineered organisms or cells, 1989 Institutional Structure, Powers and Functions Relevant Guidelines and Protocols. Other relevant laws The Biological Diversity Act, 2002 Protection of Plant Varieties and Farmer's Rights Act, 2001 Drugs and Cosmetics Act, Policy and the rules Seed Policy DGFT Notification Recent Initiatives Draft National Biotechnology Regulatory Bill 2013			
6	**Intellectual Property Rights**	8	4	
	Introduction A Brief history of IP protection TRIPS, Biotechnology and IPR Rationale for IPR Types of IPRs Patents, Copyright, Trademarks, Trade Secrets, Plant Variety protection, Geographical Indications, Farmer's Rights, Traditional Knowledge **Biotechnology Innovation and IPR** Choice of IP Patentability criteria Relevant Case law Patent protection of biotechnology in US, EU and Indian Patent Act, 1970			
	Total	**39**	**6**	

Evaluation criteria:

1. Assignment: 30%
2. Minor test: 20%
3. Major test (end semester): 50

Learning outcomes: Upon completion of this course the students will have an;

1. Awareness about ethics in research (Modules 1-2)
2. Understanding about current laws and regulations related to biodiversity and biotechnology (Modules 3-5)
3. Understanding about IPRs related to biotechnological research (Module 6)

Pedagogical Approach:
Lectures and tutorials supported by critical appraisal of original research articles, reviews, books and book chapters, hands-on-training and demonstration of online resources

Skill Set:
1. Students will have knowledge about the IPR related to agriculture and medical biotechnology.
2. Students become able to draft the application for patents, design registration, copyrights, and others.

Employability:
1. Law firms and knowledge processing organizations, IP management consultancy
2. Regulatory bodies and funding agencies
3. Medical biotechnology, Agri-biotechnology, agri-genomics and seed companies

Materials:

Suggested readings (Representative)

1. Sreenivasulu N.S. (2016)., Law relating to biotechnology, Oxford University Press, New Delhi.
2. K.D. Raju (ed.) (2007), Genetically modified organisms: Emerging law and policy in India, TERI, New Delhi
3. P. Narayan (2001), Patent Law, 3rd edn., Eastern Law House, Calcutta
4. Kamala Sankaran and Ujjwal Kumar Singh (eds.) (2008), Towards legal literacy: An introduction to Law in India, Oxford, New Delhi
5. W.R. Cornish (1999)., Intellectual Property, 4th edn., Sweet & Maxwell, London,
6. Jayashree Watal(2001)., Intellectual Property Rights in the WTO and Developing Countries, Oxford, New Delhi,
7. F.H. Erbisch and K.M. Maredia (Eds.) (2004)., Intellectual Property Rights in Agricultural Biotechnology, 2nd edn., CABI Publishing, Oxon
8. Charles Mc Mannis (ed.) (2007), Biodiversity and the Law, Earthscan, London.
9. Report of the Task Force on Application of Agricultural Biotechnology, Ministry of Agriculture, Government of India, (2004).
10. National Biotechnology Development Strategy (Draft), Department of Biotechnology, Ministry of Science and Technology, Government of India.
11. Shyam Divan and Armin Rosencranz (2005), Environmental Law and Policy in India, 2nd edn., Oxford, New Delhi. Ch.4

Required texts:
Research articles, reviews on relevant topics, websites and relevant links as provided by the instructor in lectures and tutorials

Student responsibilities:
1. Class attendance
2. Study of course materials as specified by the instructor
3. Self-study

Course Reviewers:
1. Dr. Zubair Ahmed Khan, Department of Law, Guru Gobind Singh Indraprastha University, Delhi

2. Professor Havagiray R. Chitme, Professor of Pharmacology and Head, IPR Cell, DIT University, Dehradun, India