BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI

Second Semester 2019-2020
Course Handout

06-01-2020

Course No. **: BITS F467**
Course Title **: Bioethics & Biosafety**
Instructor **: Ruchi Jain Dey and Pragya Komal**
Instructor-in-charge **: Ruchi Jain Dey**

1. Course Description: This course will address biosafety regulation, biosafety guidelines and ethical considerations related to the responsible practice of modern biotechnology and genetic engineering. The first half of the course will address the concepts underlying various biotech applications and the relevant biosafety guidelines and regulations and will be taken together with bioethical issues surrounding the implementation of each of these biotech applications.

2. Scope and Objective: Introduction to the need and issues governing biosafety, legal, ethical and social implications of human gene manipulation, guidelines for research involving transgenic organisms, socio-economic impacts of biotechnological experiments, ethics in stem cell research, organ transplants, animal experimentation and CPCSEA guidelines, environmental pollution-hazards and control, GLP & GMP guidelines, public education and participation in biosafety, IPR and patent processing.

3. Text Book (T1): Bioethics and Biosafety in Biotechnology, by *V. Sreekrishna, new age international publishers, New Delhi,* **Bioethics and Biosafety by M.Sathish.**

4. Reference Book (R1): ***Bioethics*** by Ben Mepham**;** 2nd Edn., Oxford University Press, Hampshire, Great Britain, 2008

5. Course Plan:

Lec.No.	Learning Objective	Topics to be covered	Chapter in the Text Book
1-2	To understand the need of biosafety in the field of biotechnology.	Biosafety issues related to applications of biotechnology in health and agriculture	Unit-1 T1
3-5	To understand national and international biosafety guidelines and regulations.	Biosafety guidelines and regulations; biosafety containment levels; chemical and biological hazardous materials and their safe disposal; public participation in biosafety, Workplace Hazardous Materials Information and handling (WHMIS)	Unit-1, Unit-2; T1; Research articles and reviews
6-8	To understand ethical considerations regarding environment, health and medicine.	Introduction to environmental pollution and environmental ethics, Public health, Sanitization, Medicine and Bioethics	R1:12.3.3, Unit-2, Unit-3, Research articles and reviews
9-11	To understand basics of *in vivo* genetic manipulation and assisted reproductive techniques.	Assisted reproduction techniques (ART); genetic disorders; human gene testing and manipulation; gene therapy https://www.sciencedirect.com/topics/medicine-and-dentistry/assisted-reproductive-technology	Unit 3, Unit 4; T1
12-15	To understand the basics of	Cloning technology pros and cons; animal and	Unit-3, T1,

	recombinant DNA technology and cloning.	human cloning; therapeutic and reproductive cloning; sources and types of organ transplantation	Research articles and reviews
16-18	To understand the basics, biosafety and ethical concerns related to stem cell technology.	Stem cell research; stem cell therapy and biosafety aspects, Ethics involved in Stem cell research	Unit 4, T1, Research articles and reviews
19-22	To understand the ethical concerns of GMO food and other products.	Genetically Modified Organisms (GMOs) and GM products, ethical issues and concerns	Unit 2 T1, Research articles and reviews
23-25	To understand the ethical and practical guidelines of animal based research.	Animal research and testing; GM-animals and animal models; CPCSEA guidelines	Unit 4 T1
26-28	To understand the guidelines and operational issues related to GLP and GMP	Good Laboratory & Manufacturing Practices (GLP & GMP): guidelines & implementation	Unit 5 T1
29-30	To understand national and international IPR rules and regulations.	Intellectual property, forms of IPR; international organizations, WTO, WIPO; patents and the process involved in patenting	Unit 2 T1
31-32	To understand the basics of bioethics	Need, definition and application of bioethics	Unit 1T1
33-34	To understand the societal impacts of Biotechnology	Socio-economic impacts of biotechnology: legal, ethical, social and economic impact related to human reproduction, gene manipulation and genetic testing	Unit 5 T1
35-37	To understand ethical considerations of gene manipulation based technologies and assisted reproductive techniques.	Ethical issues related to ART, genetic testing & genetic therapy	Unit 4 and 5 T1
38-39	To understand ethical considerations of human and animal cloning.	Ethical issues related to animal and human cloning, Why cloning Humans is ethically unacceptable?	Unit 5 T1, Research articles and reviews
40-41	To understand the practical guidelines and ethical considerations of laboratory animal handling.	Animal rights and laboratory animal management, CCAC guidelines on transgenic animals, need for ethical review.	Unit 3, 4 and Unit 5 T1

*supplemented with class notes

6. Evaluation Scheme:

EC No.	Evaluation Component	Duration	Weightage %	Date, Time & Venue	Nature of Component
1	Announced Quizzes	Variable	20 (40M)		CB
2	Mid-Sem	90 Min.	20 (40M)	5/3 3.30 - 5.00 PM	CB
3	Assignments	-----	10 (20M)		OB
4	Presentation	-----	15 (30M)		OB
5	Comprehensive	3 Hrs.	20 (40M) 15 (30M)	11.05.20 (FN)	CB OB

CB- Closed Book

OB- Open Book

*****Assignment topics will be allocated during lecture hours on a surprise basis. Absentees who miss the assignment allocation will NOT be given any make-up. The assignments will include written reports.

7. Chamber consultation hour: To be announced in the class.
8. Notices: All notices concerning this course will be displayed on the Biological Sciences Group notice board/CMS
9. Grading policy: Students missing one or more component of evaluation completely will be considered as having not cleared the course (NC grade). Award of grades will be guided in general by the histogram of marks. Decision on border line cases will be taken based on individual's sincerity, student's regularity in attending classes, and instructor's assessment of the student.
10. Make-up policy: Make-up for Mid-Sem and Compre will be granted only if candidate is sick and hospitalized. No make-up will be granted for Quizzes, assignments and presentation under any circumstances .
11. **Academic Honesty and Integrity Policy**: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge
BITS F467