BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI

First Semester 2022-2023
Course Handout

29-08-2022

Course No. : BITS F467
Course Title : Bioethics & Biosafety
Instructor-in-charge : Srinivasa P Kommajosyula
Instructor : Srinivasa P Kommajosyula

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. (2009)**

4. Reference Book (R1): ***Bioethics*** by Ben Mepham**;** 2nd Edn., Oxford University Press, Hampshire, Great Britain, 2008
Manfred Weidmann, Nigel Silmann, Patrick Butaye, Mandy Elschner - Working in Biosafety Level 3 and 4 Laboratories_ A Practical Introduction-Wiley-Blackwell (2013)
Lewis Vaughn - Bioethics _ principles, issues, and cases (2020)

5. Course Plan:

Lec.No.	Learning objective	Topics to be covered	Chapter in the Text Book
1-2	To understand biosafety and bioethics concepts	Introduction to the need and issues governing biosafety (arising from applications of biotechnology in health and agriculture)	Unit-1 T1
3-5	To inculcate knowledge on standard lab practices and biohazards	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
6-7	To enhance knowledge on Bioethics in decision and policy making	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

8-10	To enhance understanding of ethical and biosafety issues in biotechnology and genetic research	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
11-13		Cloning technology pros and cons; animal and human cloning; therapeutic and reproductive cloning; sources and types of organ transplantation	Unit-3, T1, Research articles and reviews
14-17		Stem cell research; stem cell therapy and biosafety aspects, Ethics involved in Stem cell research	Unit 4, T1, Research articles and reviews
18-21		Genetically Modified Organisms (GMOs) and GM products, ethical issues and concerns	Unit 2 T1, Research articles and reviews
22-24	To gain information on good lab practices and animal ethics	Animal research and testing; GM-animals and animal models; CPCSEA guidelines	Unit 4 T1
25-28		Good Laboratory & Manufacturing Practices (GLP & GMP): guidelines & implementation	Unit 5 T1
29-31	To understand the role of patent regulatory bodies and principles behind their governance	Intellectual property, forms of IPR; international organizations, WTO, WIPO; patents and the process involved in patenting	Unit 2 T1
32		Need, definition and application of bioethics	Unit 1T1
33-34		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 the ethical issues involved in different research areas	Ethical issues related to ART, genetic testing & genetic therapy	Unit 4 and 5 T1
38-39		Ethical issues related to animal and human cloning, Why cloning Humans is ethically unacceptable?	Unit 5 T1, Research articles and reviews
40-42		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	Surprise Quizzes $	Variable with classes	15 (30M)	Will be announced as course progresses	CB
2	Mid-Sem	90 Min.	25 (50M)	31/10 11.00 - 12.30PM	CB
3	Presentation with discussion*	20 min presentation + 60 min	25 (30M)	Will be announced as course progresses	OB

		discussio n			
4	Comprehensive	3 Hrs.	20 (40M) 15 (30M)	17/12 AN	CB OB

CB- Closed Book
OB- Open Book
$ Absentees will not be given make-up. Quizzes are a 10 minute activity before the scheduled lecture.
*Participation in discussion is must and will be graded based on key points or critique or summary or viewpoint or observation made by the student group not presenting

7. Chamber consultation hour: To be announced in the class.

8. Notices: All notices concerning this course will be displayed on the Google classroom/emails

9. Grading policy: Students missing two or more components 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 any evaluation component (except quizzes) will be granted only if candidate is sick and hospitalized and a letter from a doctor is issued on a hospital letter head.

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