

**BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI**  
**FIRST SEMESTER 2019-2020**  
**Course Handout**

**01-08-2019**

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

**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; 2<sup>nd</sup> Edn., Oxford University Press, Hampshire, Great Britain, 2008

**5. Course Plan:**

Lec.No	Topics to be covered	Ref. to Chapters (Unit)
1-2	Introduction to the need and issues governing biosafety (arising from applications of biotechnology in health and agriculture)	Unit-1 T1
3-5	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	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	Assisted reproduction techniques (ART); genetic disorders; human gene testing and manipulation; gene therapy <a href="https://www.sciencedirect.com/topics/medicine-and-dentistry/assisted-reproductive-technology">https://www.sciencedirect.com/topics/medicine-and-dentistry/assisted-reproductive-technology</a>	Unit 3, Unit 4; T1
12-15	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
16-18	Stem cell research; stem cell therapy and biosafety aspects, Ethics involved in Stem cell research	Unit 4, T1, Research articles and reviews
19-22	Genetically Modified Organisms (GMOs) and GM products, ethical issues and concerns	Unit 2 T1, Research articles and reviews

23-25	Animal research and testing; GM-animals and animal models; CPCSEA guidelines	Unit 4 T1
26-28	Good Laboratory & Manufacturing Practices (GLP & GMP): guidelines & implementation	Unit 5 T1
29-31	Intellectual property, forms of IPR; international organizations, WTO, WIPO; patents and the process involved in patenting	Unit 2 T1
32-33	Need, definition and application of bioethics	Unit 1T1
34-35	Socio-economic impacts of biotechnology: legal, ethical, social and economic impact related to human reproduction, gene manipulation and genetic testing	Unit 5 T1
36-38	Ethical issues related to ART, genetic testing & genetic therapy	Unit 4 and 5 T1
39-40	Ethical issues related to animal and human cloning, Why cloning Humans is ethically unacceptable?	Unit 5 T1, Research articles and reviews
41-42	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	Remarks
1	Announced Quizzes	Variable	20 (40M)		CB
2	Mid-Sem	90 Min.	20 (40M)	30/9, 1:30-3:30 pm	CB
3	Assignments	-----	10 (20M)		OB
4	Presentation	-----	15 (30M)		OB
5	Comprehensive	3 Hrs.	20 (40M)	05.12.19 FN	CB
			15 (30M)		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

**Instructor-in-charge**  
**BITS F467**