

BIOETHICS & IPR
(BIOT 4231)

Time Allotted : 2½ hrs

Full Marks : 60

Figures out of the right margin indicate full marks.

*Candidates are required to answer Group A and
any 4 (four) from Group B to E, taking one from each group.*

Candidates are required to give answer in their own words as far as practicable.

Group – A

1. Answer any twelve:

12 × 1 = 12

Choose the correct alternative for the following

- (i) What ethical theory applies to the statements “Donated organs should be made available to patients on the basis of medical need and not on the basis of social status or other consideration”
 - (a) Justice
 - (b) rights
 - (c) double effect
 - (d) preference utilitarianism.
- (ii) According to the Belmont Report, research involving human subjects demands
 - (a) Informed consent
 - (b) Risk assessment
 - (c) Benefit assessment
 - (d) Subject selection.
- (iii) Scenario: A research team is proposing a new drug trial. The protocol requires all potential participants to be fully informed about the risks, benefits, and alternatives before signing consent forms. This requirement primarily addresses which ethical concept?
 - (a) Casuistry
 - (b) Genetic Justice
 - (c) Informed Consent
 - (d) Resource Allocation
- (iv) A person is entitled to apply for patent if he is
 - (a) True and first inventor
 - (b) An assignee of the true and first inventor
 - (c) legal representative of the person
 - (d) All of these.
- (v) Which of the following would you not expect to find in a Biosafety Level 1 Lab?
 - (a) Non-pathogenic *Escherichia coli*
 - (b) West Nile Virus
 - (c) Canine Hepatitis
 - (d) *S. cerevisiae*.
- (vi) The Patent office falls under the which ministry of India?
 - (a) Science and Technology
 - (b) Commerce and Industry
 - (c) Finance Ministry
 - (d) Human Resource Development.

- (vii) By India patent act 1970, a patent gives protection for
 (a) 14 years from the date of publication
 (b) 20 years from the date of grant
 (c) 21 years from the next calendar year in which the patent is granted
 (d) none of these
- (viii) Choose the most appropriate statement among the following: Investors prefer which form of the legal structure of an enterprise and why
 (a) Proprietorship because it gives absolute liberty to the proprietor for execution and the personal assets of the proprietor can be attached in case of default.
 (b) Partnership because it has all attributes of proprietorships and more than one founders
 (c) Private limited company because the personal assets of shareholders cannot be attached to meet company obligations and it can induct new investors as shareholders.
 (d) Public limited since it can list its shares to stock exchanges.
- (ix) What is a unicorn?
 (a) A startup whose valuation has reached US \$ 10.00 billion or more.
 (b) A startup whose valuation has reached US \$ 1.00 billion or more.
 (c) A startup with 1,000 employees or more.
 (d) A startup whose annual turnover is US \$ 10.00 billion or more.
- (x) A biotech startup has developed a novel point-of-care diagnostic device. Which of the following is the most crucial core component for ensuring the venture's long-term success
 (a) The founder's detailed list of competitors' past failed product launches.
 (b) A patented technology, a clearly defined market need, and a viable revenue model.
 (c) An excessively large R&D budget with no immediate milestones defined.
 (d) A board of advisors comprised solely of academic researchers with no industry experience.

Fill in the blanks with the correct word

- (xi) To categorize entrepreneurship on a large scale, the annual turnover should be above Rs. _____ core.
- (xii) Grameen Bank by Muhammad Yunus is an example of _____ entrepreneurship.
- (xiii) Full form of "WIPO" _____.
- (xiv) TRIPS establishes minimum standards for the availability, scope, and use of _____ forms of intellectual property.
- (xv) According to the Indian version, copyright is valid for a period of _____ years after the death of the author.

Group - B

2. (a) Explain different Environmental Ethical Principles.

[[CO2](Explain /IOCQ)]

- (b) What is the difference between Intrinsic and Instrumental Values? [[CO2](Apply/IOCQ)]
- (c) Explain about HUGO Ethics Committee Statement on gene therapy research along with its problems. [[CO2](Explain/HOCQ)]
- 4 + 4 + 4 = 12**
3. (a) Bioethics tools are categorized as theories and principle approaches. What are the five theories and four principles? Discuss about anyone theory and anyone principle that you have mentioned. [[CO1](Analyse/IOCQ)]
- (b) Discuss about of the following with real life examples in the context of bioethics: roots of honours and integrity in biotechnology. [[CO1](Discuss/IOCQ)]
- (2 + 2 + 2 + 2) + 4 = 12**

Group - C

4. Write short notes of the following:
(i) Guide lines of DBT, (ii) Good clinical practices in India, (iii) Biosafety regulations in India, (iv) Protection of public health in India. [[CO3](Understand/LOCQ)]
- (4 × 3) = 12**
5. (a) Discuss guide lines of ICMR for biomedical and health research involving human participants. [[CO3](Understand/IOCQ)]
- (b) What do you understand by good laboratory practice (GLP)? [[CO3](Remember/LOCQ)]
- (c) Explain in brief about the function of WHO. [[CO3](Remember/IOCQ)]
- 4 + 4 + 4 = 12**

Group - D

6. (a) Why product of nature cannot be patented? [[CO4](Remember/HOCQ)]
- (b) What do you understand by product patent and process patent? [[CO4](Remember/IOCQ)]
- (c) Explain the rights and obligation of patentee. [[CO4](Remember/IOCQ)]
- 2 + (3 + 3) + (2 + 2) = 12**
7. (a) Explain the following in detail with reference to patentable invention: Novelty, non-obviousness, utility and feasibility. [[CO4](Understand/IOCQ)]
- (b) What do you understand by the term “most favoured nation”? [[CO4](Understand/IOCQ)]
- 8 + 4 = 12**

Group - E

8. Write a plan to start a start-up CRO in biotechnology. What kind of IPR you need for that? Write the names of different types of IPR? Explain the requirements of different three types of IPR that you have mentioned, with examples. [[CO6](Explain/HOCQ)]
- [3 + 1 + 2 + (3 × 2)] = 12**

9. (a) Design a trade mark for a sunscreen cream whose target group consider only men. [[C06](Analyse/HOCQ)]
- (b) What you will do if any other company mimics your product? [[C06](Remember/LOCQ)]
- (c) Discuss the appropriateness of the support mechanism available for entrepreneurship in India. [[C06](Apply/IOCQ)]
- 4 + 4 + 4 = 12**
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Cognition Level	LOCQ	IOCQ	HOCQ
Percentage distribution	20.83	56.26	22.91