

Introduction to Ethics in Biotechnology

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Study guide – key concepts, questions, and frameworks

1. Why Ethics Matters in Biotechnology

Aspect	Why It's Important
Human health	Decisions affect safety of medicines, vaccines, gene therapies, and diagnostic tools.
Environmental impact	Release of engineered organisms can alter ecosystems, biodiversity, and food chains.
Social justice	Access to biotechnological advances can widen or narrow health and economic inequalities.
Public trust	Transparent, responsible practices maintain confidence in science and policy.
Legal & regulatory compliance	Ethical standards guide laws, patents, and international agreements.

2. Core Ethical Principles (applied to biotech)

Principle	Definition	Typical biotech applications
Beneficence	Promote well-being and maximize benefits.	Developing life-saving drugs, improving crop yields.
Non-maleficence	Avoid causing harm.	Safety testing of GMOs, preventing off-target effects in gene editing.
Autonomy	Respect individuals' right to make informed choices.	Informed consent for clinical trials, patient data privacy.
Justice	Fair distribution of benefits and burdens.	Equitable access to therapies, global sharing of vaccine technology.
Respect for Persons	Recognize intrinsic value of all living beings.	Consideration of animal welfare in research, respect for indigenous knowledge.

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Principle	Definition	Typical biotech applications
Precautionary Principle	When impacts are uncertain, err on the side of caution.	Field trials of gene-drive insects, release of synthetic biology products.

3. Major Ethical Issues in Biotechnology

Issue	Description	Key Questions
Genetic Modification (GM) of Organisms	Altering DNA of plants, animals, microbes.	<i>What are the long-term ecological risks?</i> <i>How will GM crops affect smallholder farmers?</i> <i>Should germline editing be allowed?</i>
Human Gene Editing (CRISPR, etc.)	Editing embryos, germline, or somatic cells.	<i>How to prevent “designer babies”?</i>
Synthetic Biology & Bio-fabrication	Designing new biological parts or whole organisms.	<i>What containment measures are needed?</i> <i>Who owns the intellectual property?</i> <i>How to protect donor anonymity?</i>
Biobanking & Data Privacy	Storing biological samples & genomic data.	<i>Who decides future uses of stored samples?</i>
Dual-Use Research	Research that can be used for both beneficial and harmful purposes.	<i>How to balance scientific openness with security?</i>
Patents & Commercialization	Intellectual property rights over genes, organisms, or processes.	<i>Do patents hinder access to essential medicines?</i>
Animal Welfare	Use of animals in research, production, and testing.	<i>Are alternatives (organoids, computer models) sufficient?</i> <i>What monitoring systems are required?</i>
Environmental Release	Field trials and commercial release of engineered organisms.	<i>How to assess cumulative impacts?</i>

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4. Ethical Decision? Making Frameworks

1. Stakeholder Analysis

- Identify all parties (patients, farmers, indigenous groups, future generations, ecosystems).
- Map interests, power, and potential impacts.

2. Risk?Benefit Assessment

- Quantify potential health, ecological, and social benefits.
- Estimate probability and magnitude of harms.
- Use *probabilistic