D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 18

Bioethics



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

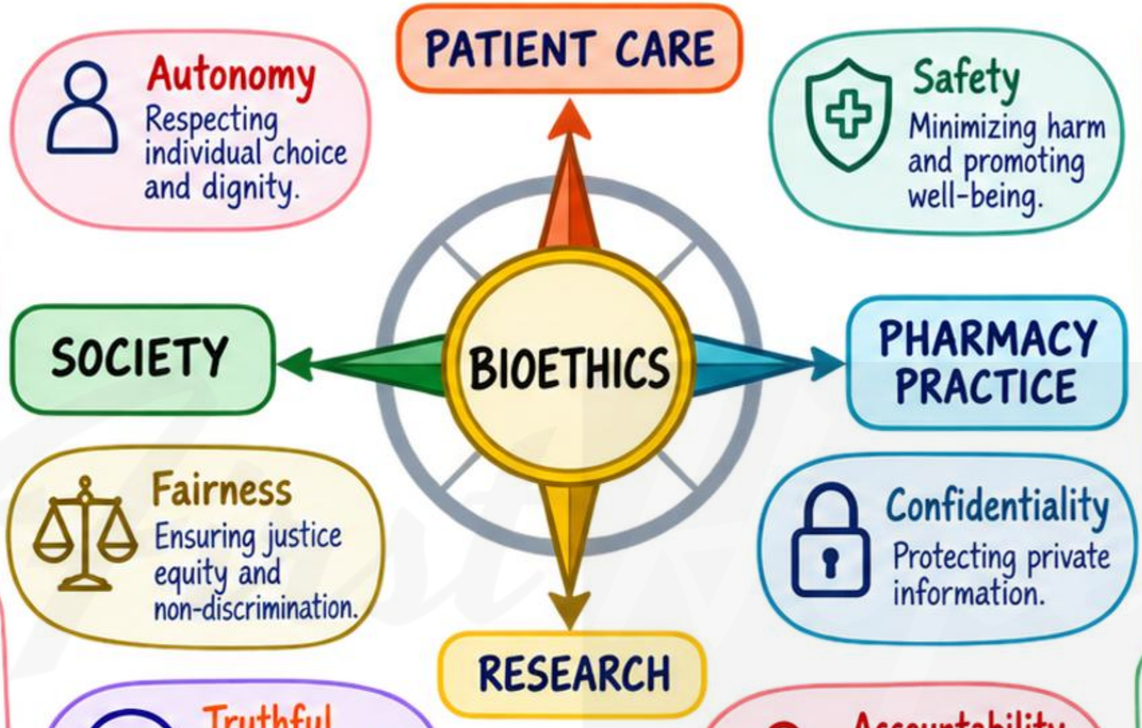
BASIC CONCEPTS OF BIOETHICS

MEANING

- Bioethics is the systematic study of moral questions in biology, healthcare, medicines, biotechnology and research.
- In pharmacy, it guides how pharmacists. researchers and healthcare professionals protect human life, dignity, rights, safety and well-being.
- **ETHICS** asks: What should be done, why is it right, who may be helped or harmed, and is the decision fair?

WHY IT MATTERS IN PHARMACY

- Protects patient rights and safety
- helps solve difficult choices
- controls confficts of interest
- supports ethical clinical trials
- builds trust in pharmacists and healthcare.



MAIN AREAS

- **PATIENT CARE** — consent, treatment choices, truth-telling and safe medicines.
- **PHARMACY PRACTICE** — accurate dispensing, counselling, confidentiality and professional accountability.
- **RESEARCH ETHICS** — voluntary participation, independent review, risk minimization and fair selection.
- **PUBLIC HEALTH & BIOTECHNOLOGY** — fair access, organ donation, reproduciite choices, genetics, stem-cell research and responsible innovation.

CORE QUESTIONS BEFORE ACTION

- Is the person informed and free to choose?
- Will beonfit be maximized and harm minimized?
- Is access fair?
- Is private information protected?
- Can the decision be explained and documented?

PHARMACY DECISION PROCESS

Prescription review
Check for accuracy. appropriateness and safety.

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Counselling
Provide clear information and support informed choice.

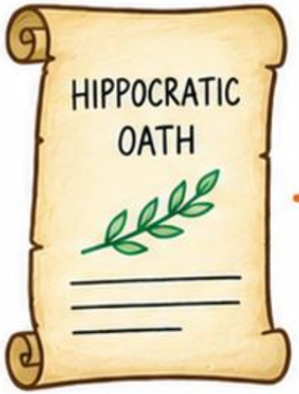
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Privacy
Maintain confidentiality of patient information.

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Reporting
Report errors, adverse effects and ethical concerns.

HISTORY OF BIOETHICS



ANCIENT & PRE-MODERN

the Hippocratic tradition and religious / philosophical duties stressed benefit, confidentiality and avoiding harm, but research protections were not yet a modern system.



1947 NUREMBERG CODE

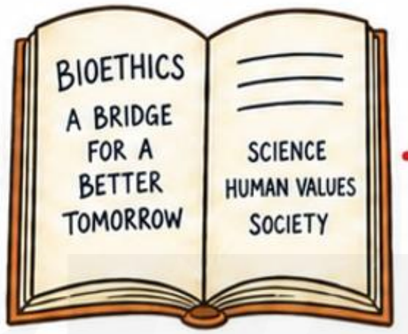
After the Doctors' Trial exposed coercive experiments during World War II, the Code made voluntary informed consent central and required scientifically justified research with avoidable harm reduced.



1964 DECLARATION OF HELSINKI

The World Medical Association set principles for medical research involving human participants: participant welfare, sound science, independent ethics review and informed consent.

CURRENT NOTE: the official version is the **2024** revision.



1970–71 MODERN BIOETHICS

Van Rensselaer Potter helped popularise bioethics as a bridge between biological knowledge and human values.

1979

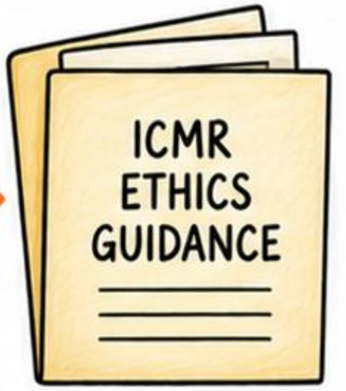
Beauchamp and Childress developed the influential four-principles approach.



1979 BELMONT REPORT

Issued after serious research abuses in the USA, including Tuskegee: Respect for Persons • Beneficence • Justice.

Applications: informed consent • risk-benefit assessment • fair selection.



INDIA ICMR ETHICS GUIDANCE

ICMR statements and guidelines developed in **1980**, **2000** and **2006**, followed by the comprehensive National Ethical Guidelines in **2017**. Later topic-specific guidance supplements the **2017** core guideline.

FROM PROFESSIONAL DUTY TO PARTICIPANT RIGHTS

PRINCIPLES OF BIOETHICS

AUTONOMY

respect a capable person's informed choices.

Pharmacy example: explain purpose, benefits, risks and alternatives; respect an informed refusal subject to law and genuine emergencies.





BENEFICENCE

actively promote the patient's good.

Pharmacy example: choose and counsel for safe, effective and suitable therapy, not convenience or profit.



NON-MALEFICENCE

avoid or minimize preventable harm.

Pharmacy example: detect allergy, contraindication, overdose or interaction; clarify the prescription before dispensing.



JUSTICE

distribute benefits, burdens and healthcare resources fairly.

Pharmacy example: provide equal, non-discriminatory access to essential medicines and services.



SUPPORTING DUTIES

VERACITY



tell the truth in clear words; do not hide important risk or error.

FIDELITY



keep professional promises, act loyally and maintain trust.

CONFIDENTIALITY



protect patient information; disclose only with consent or a valid ethical / legal basis.

SIMPLE ETHICAL DECISION PATH

1. Gather clinical and social facts
2. identify the conflict and stakeholders
3. compare options using the principles
4. discuss with the patient and team
5. choose, document, monitor and review.

No principle works alone; difficult cases require a reasoned balance, applicable law and patient-centred communication.

ICMR'S NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS (2017)

ICMR 2017 – FIRST SIX OF 12 GENERAL PRINCIPLES

The four basic principles are expanded into 12 general principles for research involving human participants, their biological material or data.

1 ESSENTIALITY

Use human participants only when the research is necessary after considering alternatives; an independent Ethics Committee must vet it.

2 VOLUNTARINESS

Participation or withdrawal is the person's free choice; informed consent safeguards that choice.

3 NON-EXPLOITATION

Select participants fairly, distribute burdens and benefits equitably, and give extra safeguards to vulnerable groups.



4 SOCIAL RESPONSIBILITY

Plan research so it does not create or deepen social divisions or disturb community harmony.

5 ENSURING PRIVACY AND CONFIDENTIALITY

Respect personal space and keep identity and records confidential, with access limited to authorised persons and only valid exceptions.

6 RISK MINIMIZATION

Researchers, sponsors, institutions and ECs must reduce risk at every stage and arrange appropriate care and compensation if harm occurs.

SCOPE

Applies to biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material or data.

Human participants | Biological material | Data

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