

3.1 A brief history of medical research and its ethics

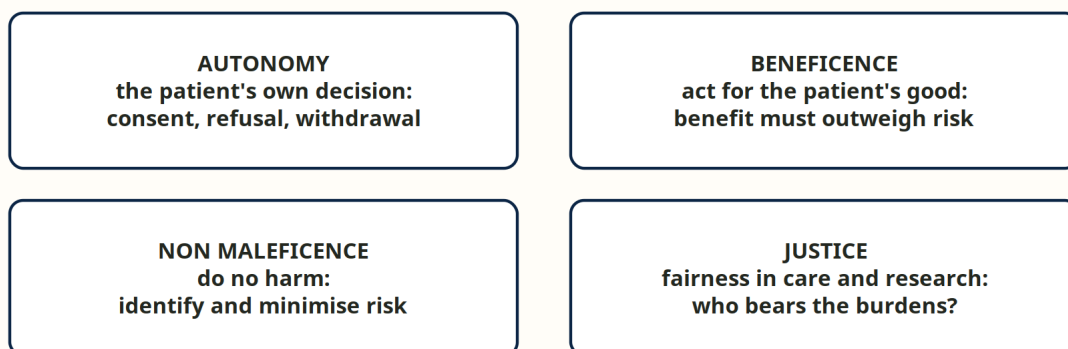
Medical ethics is as old as organised medicine: the Hippocratic tradition bound the physician to benefit the patient and to do no harm, and professional codes in many cultures carried versions of the same duties.

Medical research as a distinct activity, experimenting on patients to learn rather than only to treat, grew with scientific medicine in the nineteenth and twentieth centuries, and its ethics lagged its power. The abuses of the Second World War produced the Nuremberg Code (1947), the first international statement that the voluntary consent of the subject is absolutely essential. The Declaration of Helsinki followed in 1964 (Unit 5). The lag continued in peacetime democracies too: the Tuskegee study in the United States (1932 to 1972) observed the natural course of untreated syphilis in poor Black men for forty years, withholding effective treatment long after penicillin existed, and its exposure in 1972 reshaped American research law. The pattern of the history is consistent: each protection in this unit and Unit 5 was written after a failure, which is why the rules read as they do and why committees treat them as floors, not aspirations.

3.2 Values in medical ethics: the four principles

Modern medical ethics is organised around four values, the framework this unit is built on. **Autonomy**: the patient's right to decide what is done to his own body and to direct his own treatment, grounded in respect for persons. **Beneficence**: the duty to act for the patient's benefit, to do good. **Non maleficence**: the duty to do no harm, the older Hippocratic command. **Justice**: fairness in distributing the benefits and burdens of medicine and research, in subject selection as much as in treatment. In research, the four principles translate into the working rules of this degree: autonomy into informed consent, beneficence and non maleficence into the risk benefit judgement every protocol must pass, and justice into fair selection of subjects, so that the burdens of research do not fall habitually on the poor and voiceless while the benefits flow elsewhere.

The Four Principles of Medical Ethics



No principle outranks the others by rule: the ethics committee balances them.

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Figure: The four principles. No principle outranks the others by rule; the work of ethics is balancing them in the concrete case, which is why committees exist.

3.3 Autonomy

Autonomy is the principle that a competent person is the author of decisions about his own body and care. It requires capacity (the patient can understand, deliberate and communicate a choice), information (the material facts a reasonable person would want), and freedom from coercion and manipulation. Its operational forms are informed consent (section 3.7), the right to refuse treatment, the right to withdraw from research at any time without penalty, and respect for advance decisions. Autonomy is limited where capacity is absent (children, unconscious patients, some psychiatric illness), where surrogates and safeguards take over, and where one person's choices would gravely harm others, as in some public health emergencies. For the researcher, the practical meaning is sharp: a scientifically perfect study on unconsenting subjects is ethical failure regardless of its results, because the subjects were used as means only.

3.4 Beneficence, non maleficence, and the conflicts between them and autonomy

Beneficence obliges the clinician and researcher to act for the subject's good: to offer interventions expected to help, to design studies whose knowledge is worth having, and to rescue where rescue is possible. **Non maleficence** obliges them first to avoid harm: foreseeable risks must be identified, minimised and justified, and some harms may not be imposed for knowledge at any price. The two are the twin terms of the risk benefit judgement required of every protocol: expected benefit must outweigh foreseeable risk, and the ratio is judged by the ethics committee, not by the investigator with a thesis deadline.

Conflicts between autonomy and beneficence or non maleficence are the daily texture of medical ethics, and the syllabus names them deliberately. A competent patient refuses a transfusion that would save his life: beneficence says transfuse, autonomy says the body is his; the settled answer in modern practice is that the competent refusal governs, however it grieves the team. In research the conflict reverses direction: the investigator's wish to complete a valuable study (a beneficent end) cannot override a subject's autonomous wish to withdraw. Where the patient lacks capacity, surrogates decide in his best interests, the beneficence standard. The principles do not dissolve these conflicts; they name the values at stake so the decision is reasoned rather than improvised, and hard cases go to the ethics committee (section 3.11), not to individual conscience alone.

3.5 Double effect

The **doctrine of double effect** governs actions that foreseeably produce both a good and a harmful effect. An act with a bad side effect is permissible, on the classic conditions, when the act itself is good or neutral, the good effect is intended and the bad merely foreseen (not intended, and not the means to the good), and the good is proportionate to the harm risked. The stock medical example is adequate pain relief with opioids in a dying patient: relief is intended; a possible hastening of death through respiratory depression is foreseen and accepted, not sought; and the relief is proportionate. Double effect is the line orthodox ethics draws between palliative care and euthanasia (the next section), and students should be able to state both the doctrine and its critics' objection, that intention is too private a thing to bear so much moral weight.

3.6 Euthanasia

Euthanasia, literally a good death, is the deliberate ending of a patient's life to relieve suffering. The distinctions that structure the debate: **active** euthanasia (a lethal act, such as an injection given to end life) against **passive** (withholding or withdrawing life sustaining treatment and letting the disease take its course); **voluntary** (at the competent patient's request), **non voluntary** (the patient cannot request, as in permanent coma) and **involuntary** (against the patient's wishes, condemned by all sides). Orthodox medical ethics and Indian law prohibit active euthanasia; the Indian position, settled by the Supreme Court,

permits **passive euthanasia** under strict safeguards (Aruna Shanbaug, 2011) and recognises **advance directives or living wills** refusing life sustaining treatment, with a laid down procedure (Common Cause, 2018). The research relevance is indirect but real: end of life studies, palliative research and withdrawal of futile treatment all work inside this framework, and an ethics committee will require the protocol to state which side of the line it stays on.

3.7 Informed consent

Informed consent is the process by which autonomy is exercised in treatment and research: a competent person, given the material information in understandable language, freely agrees. Its elements are constant across the codes (and are stated as principles in Unit 5): the nature and purpose of the procedure or study, what participation involves, the foreseeable risks and discomforts, the expected benefits (stated honestly, including that a trial may offer the subject none), the alternatives, the safeguards of confidentiality, compensation and treatment for research related injury where applicable, the voluntary character of participation, and the right to withdraw at any time without affecting care. Consent for research is written and documented, obtained before any study procedure, and treated as a continuing process rather than a signature: new information (a safety signal, a protocol change) renews it. Special rules protect those who cannot consent for themselves: children (parental consent plus the child's assent where capable), unconscious patients (legally authorised representative), and vulnerable populations, where committees add safeguards against inducement and coercion. A consent obtained by pressure, by incomplete disclosure or from a person who could not understand it is not consent, and research resting on it is unethical whatever its data show.

3.8 Confidentiality

Confidentiality is the duty to guard the patient's and the subject's information: identity, records, samples and data. It rests on autonomy (the information is the person's own) and on trust (patients who fear disclosure conceal facts their doctors need). In research it is engineered into the study: coded identifiers instead of names on analysis files, restricted access, secure storage, publication in aggregate so that no individual can be recognised, and special care with genetic and stigmatising information. Breaches are justified only narrowly: the patient's own consent, a legal duty, or a serious and identifiable risk to others that disclosure can avert, and even then the minimum necessary information goes to the minimum necessary audience. The modern setting adds digital duties: databases and online practices (section 3.13) must be secured, and a confidentiality failure online is a failure at scale.

3.9 Criticisms of orthodox medical ethics

The syllabus asks for the **criticisms of orthodox medical ethics**, the four principle, rule bound tradition itself. The standard criticisms are these. That principlism is a checklist: it names values but gives no rule for ranking them when they conflict, so decisions can be rationalised after the fact. That it is culturally narrow: built on individual autonomy, it fits awkwardly in societies where decisions are made by families and communities (section 3.12). That it is cold: real care involves emotion, virtue and relationship (the ethics of care and virtue ethics are rival accounts). That its rules bend under institutional pressure: hospitals and sponsors have interests, and ethics language can decorate decisions made for money or reputation. And the feminist and communitarian critiques add that the tradition long ignored who actually bears medicine's burdens. The student need not abandon the framework, it remains the working language of committees and courts, but should hold it as a tool with known limits, not as a machine that outputs right answers.

3.10 Communication and conflict resolution

Communication is named in the syllabus because most ethical failures in practice are communication failures first: consent taken without understanding, bad news broken brutally or withheld, families and teams working from different facts. Its skills are concrete: listening before informing, plain language without jargon, checking understanding, honesty about uncertainty, time for questions, and documented discussion. Where values collide (within a family, between team members, between patient and institution), **conflict resolution** follows a discipline of its own: establish the facts, name the values in conflict, hear every party including the patient, seek the option that honours the most principles, use the ethics committee as mediator and forum, and document the decision and its reasons. The phrases of the syllabus print "control resolution"; it is read and taught here as conflict resolution, the standard topic between communication and guidelines (see the verification record).

3.11 Guidelines and ethics committees

Ethical rules reach the bedside through **guidelines** and **ethics committees**. The guideline stack for an Indian researcher runs from the international codes (Nuremberg, the Declaration of Helsinki of Unit 5, the CIOMS guidelines) through national instruments (the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017; the New Drugs and Clinical Trials Rules, 2019 for drug trials) to institutional standard operating procedures. The **ethics committee** (Institutional Ethics Committee for human research; Institutional Animal Ethics Committee under CPCSEA for animal work, Unit 4) is the body that applies them: an independent, multidisciplinary committee, including lay and legal members, that reviews the protocol before the study starts, judges the risk benefit ratio, the consent process and the protection of vulnerable subjects, and continues oversight through progress reports and safety information. Approval is prospective; a study begun without it cannot be cured retrospectively, and journals and universities refuse its fruits. For the M.Pharm student the committee is not a hurdle but the institution that makes the research defensible.

3.12 Cultural concerns and truth telling

Cultural concerns arise because ethical practice is enacted inside cultures. Family centred decision making, religious convictions about the body, death, blood, diet and gender of the treating clinician, and differing understandings of illness can all pull against the individualist defaults of the codes. The working position is respect without surrender: learn the patient's framework, involve the family as the patient wishes, adapt communication and logistics where possible, and hold the floor of the principles themselves (a competent refusal stands even when the family disagrees; harmful practices are not performed because they are customary). **Truth telling** is the sharpest cultural case. Orthodox ethics requires honest disclosure of diagnosis and prognosis to the patient; some families, from protective motives, ask that a grave diagnosis be withheld from the patient. The orthodox answer respects the patient's own wish as the controlling one: ask the patient how much he wants to know and who should be told, and follow that. Lying to a competent patient at others' request treats him as a child in his own illness; blunt disclosure against his stated wish is its own cruelty. The skill is finding, with the patient, the truth he wants at the pace he wants it.

3.13 Conflicts of interest, referral, vendor relationships and online practice

The last items of the syllabus unit are the professional practice problems. A **conflict of interest** exists whenever a secondary interest (money, publication, promotion, a sponsor's favour) risks distorting a primary duty (the patient's good, the integrity of the research). The management is disclosure first, then refusal or independent oversight where disclosure is not enough; undisclosed conflicts, not conflicts themselves, are the scandal. **Referral** must be governed by the patient's interest: referring to the best appropriate provider, never split fees or referral commissions, which convert clinical judgement into trade. **Vendor relationships** (with pharmaceutical and device companies: gifts, hospitality, sponsored travel,

consultancy) are regulated by professional codes precisely because marketing works; the researcher declares industry ties in every publication and presentation. **Online business practices** extend the same duties to the digital front: honest advertising without exaggerated claims, teleconsultation within competence and law, protection of patient data online (section 3.8), and professional conduct on public platforms. The principles are old; only the shopfront is new.

3.14 Treatment of family members, sexual relationships and fatality

Three boundary problems close the unit. **Treating family members and oneself** is discouraged by professional guidance except in minor or emergency situations: objectivity is compromised, intimate history is under taken, the relative may conceal or the doctor may over investigate, and records and consent become informal. **Sexual relationships** with patients are prohibited absolutely: the power imbalance between doctor and patient vitiates consent, and the prohibition extends, with graded rules, to former patients and to patients' close relatives; the same boundary logic binds researchers and the subjects in their power. **Fatality**, the death of a patient, carries duties of its own: honest and prompt communication with the family, accurate certification and documentation, respect for the body and for the family's religious and cultural practices, disclosure of error where error occurred (with the institution's process, not private improvisation), and care for the team's own moral residue. A researcher analysing mortality data should remember that every row of the outcome table was one of these events.

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