RESEARCH ETHICS FOR MEDICAL STUDENTS

Ethical Requirements, Review Committees, and Informed Consent

Protecting the rights, safety, and dignity of every research participant

SESSION OVERVIEW

Learning Objectives

By the end of this session, you should be able to:

1. Explain why ethical oversight of research involving humans is necessary
2. List and describe the core requirements for ethical research
3. Describe the role, composition, and approval process of Ethical Review Committees
4. Define informed consent and identify its essential elements
5. Recognise vulnerable populations and special consent considerations
6. Identify common pitfalls that compromise research ethics

Why Research Ethics Matter

History teaches why oversight is not optional

Without independent review and genuine consent, even well-intentioned researchers can cause lasting harm.

Nazi Human Experiments (1940s)

Prisoners subjected to brutal, non-consensual experiments — led directly to the Nuremberg Code (1947).

Tuskegee Syphilis Study (1932–1972)

a 40-year medical experiment conducted from 1932 to 1972 by the U.S. Public Health Service. It watched 600 impoverished Black sharecroppers in Alabama—399 with untreated syphilis and 201 without—while deliberately withholding effective treatment, including penicillin, to document the natural course of the disease — exposed failures in consent and justice.

Willowbrook Hepatitis Study (1956–1970)

Institutionalized children (intellectual disabilities) were deliberately infected with hepatitis to understand the disease and tests vaccines — raised urgent questions about vulnerable participants.

Landmark Codes That Shaped Research Ethics

1947

Nuremberg Code

First international code: voluntary consent is "absolutely essential."

1964

Declaration of Helsinki

World Medical Association standard; introduced independent ethics committee review.

1979

The Belmont Report

Defined 3 core principles: Respect for Persons, Beneficence, Justice.

1996+

ICH-GCP Guidelines

Harmonised international Good Clinical Practice standards, still used today.

Core Ethical Principles (The Belmont Report)

Respect for Persons

Individuals are autonomous agents; those with diminished autonomy are entitled to extra protection.

- A researcher fully explains a clinical trial's risks, benefits, and alternatives to a potential participant, then lets them decide freely whether to enroll (informed consent).
- A study involving prisoners includes extra safeguards, since incarceration could make "voluntary" consent coercive (e.g., fear that refusal affects parole).
- A pediatric study requires parental permission plus the child's assent (age-appropriate agreement), since children can't fully consent on their own.
- A participant with early-stage dementia is given a simplified consent process and a trusted proxy is involved to protect their interests.

Applied via: Informed consent

Beneficence

Maximize possible benefits and minimise possible harms to participants.

- Before approving a drug trial, an IRB (Institutional Review Board) requires preliminary animal studies to establish a reasonable safety profile before testing in humans.
- A study is designed with a data safety monitoring board that can stop the trial early if participants are being harmed or if one treatment arm is clearly superior.
- Researchers choose the least invasive method to collect data (e.g., a survey instead of a blood draw) when it would answer the same research question.
- A psychology study on stress avoids inducing severe emotional distress when a milder induction would still yield valid results.

Applied via: Favorable risk–benefit ratio

Justice

The burdens and benefits of research must be distributed fairly across society.

- Historically, the Tuskegee Syphilis Study is the classic *violation* example: Black men were denied treatment and left to suffer effects of the disease, unfairly burdening a vulnerable population without benefit to them.
- A fair approach: a study on a new Alzheimer's drug recruits participants broadly rather than only from a nearby low-income clinic just because it's a "convenient" population.
- Ensuring that if a study is testing a treatment for a condition common among a specific community, that same community has access to participate in and benefit from the resulting treatment.
- Not excluding women or minorities from clinical trials without scientific justification, since exclusion can mean they don't benefit from resulting medical advances.

Applied via: Fair subject selection

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Ethical Requirements

The conditions a study must satisfy to be ethically justifiable

Seven Requirements for Ethical Research

Framework adapted from Emanuel, Wendler & Grady (2000)

1. **Social & Scientific Value**
2. **Scientific Validity**
3. **Fair Subject Selection**
4. **Favorable Risk–Benefit Ratio**
5. **Independent Review**
6. **Informed Consent**
7. **Respect for Enrolled Participants**

All seven must be satisfied — not just informed consent — for a study to be ethical.

Social Value & Scientific Validity

Social & Scientific Value

- The research question must address a genuine health problem
- Results should be generalisable or lead to improved treatment, diagnosis, or prevention
- Justifies exposing participants to risk, time, and inconvenience
- Prevents wasted resources on trivial or unanswerable questions

Scientific Validity

- Sound methodology: clear hypothesis, appropriate design, adequate sample size
- Valid, reliable measurement tools and statistical analysis plan
- Achievable with available resources and researcher expertise
- Invalid studies cannot be ethical — they expose participants to risk with no real scientific gain

Fair Subject Selection

Participants should be chosen based on the scientific goals of the study — not convenience, vulnerability, or privilege.

1

Avoid over-selection of vulnerable groups

Prisoners, students, or economically disadvantaged people should not bear a disproportionate share of research risk simply because they are accessible.

2

Avoid unjustified exclusion

Women, minorities, older adults, and people with disabilities should not be excluded without a valid scientific or safety reason.

3

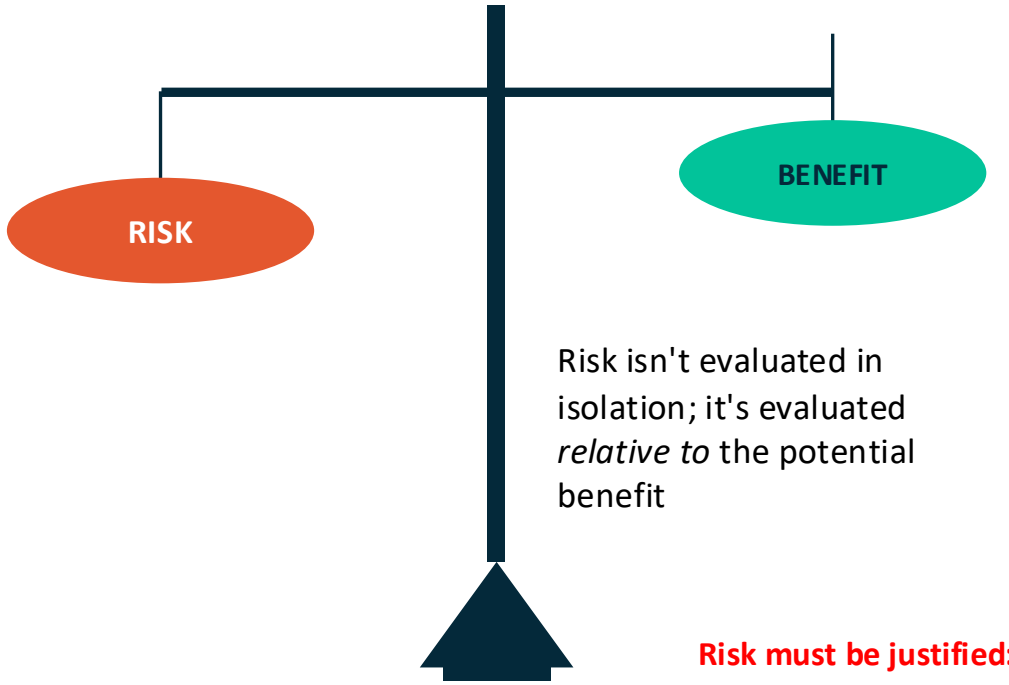
Inclusion/exclusion criteria must be scientifically justified

Eligibility rules should relate directly to the research question, not administrative convenience.

1. A study testing a new insulin regimen for Type 2 diabetes excludes people with severe kidney disease?
2. Anyone who doesn't have reliable transportation to the clinic (makes follow-up visits easier for staff, but has nothing to do with the biology of insulin response).

Favorable Risk–Benefit Ratio

Risks to participants must be minimised, and reasonable in relation to anticipated benefits — to the participant and to society.



Risk isn't evaluated in isolation; it's evaluated *relative to* the potential benefit

Minimise risk: Use the safest procedures consistent with sound design; avoid unnecessary tests or procedures.

A study wants to measure inflammation levels in participants with a chronic illness. Two options exist:
Option A: Draw a small blood sample via a standard venipuncture (minor discomfort, very low risk).
Option B: Perform a tissue biopsy to directly sample inflamed tissue (more invasive, carries risk of bleeding, infection, and scarring).

Maximise benefit: To participants directly (where possible) and to society through generalisable knowledge.

benefit directly to participants:
A clinical trial for a new cancer therapy enrolls patients who have exhausted standard treatment options. Participants may directly benefit because.

benefit to society through generalizable knowledge:
A study testing whether a low-cost antiviral reduces complications from a common childhood illness in a rural population

Risk must be justified: Greater risk is only acceptable with correspondingly greater potential benefit — reviewed by the ethics committee.

1. A study asks participants to complete a 20-minute anonymous survey about diet habits to inform nutrition guidelines. The risk is minimal (mild boredom, no physical or psychological harm), so even a modest benefit (incremental improvement in dietary knowledge) is enough to justify it. An IRB would approve this quickly, often via expedited review.
2. A Phase 1 trial for an experimental cancer drug carries significant risk: unknown toxicity, potential severe side effects, even life-threatening complications. This is only ethically justified because:

Independent Review, Informed Consent & Respect

Independent Review

An ethics committee unaffiliated with the study evaluates it for social value, validity, and risk–benefit balance before it begins.

Informed Consent

Participants voluntarily agree to take part after understanding the purpose, procedures, risks, and benefits (detailed later in this session).

Respect for Enrolled Participants

Ongoing right to withdraw, protection of privacy and confidentiality, monitoring of wellbeing, and disclosure of new findings that may affect them.

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Ethical Review Committees & Approval

Independent gatekeepers that protect participants before research begins

What Is an Ethical Review Committee?

Also known as:

- Institutional Review Board (IRB) — USA
- Research Ethics Committee (REC) — UK/EU
- Independent Ethics Committee (IEC) — global trials
- Human Research Ethics Committee (HREC) — Australia
- Institutional Review Board (IRB) — Jordan

A committee of medical, scientific, and non-scientific members that independently reviews research involving humans to ensure participants' rights, safety, and wellbeing are protected.

✓

Independence

Members are unaffiliated with the study, removing conflicts of interest.

✓

Authority

No human research may begin — or continue — without its approval.

✓

Accountability

Provides an auditable record that ethical standards were checked.

Who Sits on the Committee?

Regulations (e.g., ICH-GCP) require a multidisciplinary membership — typically 5 or more members:

M

Medical / Scientific Experts

Clinicians and researchers who assess scientific validity and clinical risk

L

Legal Expert

Advises on regulatory compliance, liability, and participant rights

C

Lay / Community Member

A non-scientific voice representing participants' and public perspective

E

Ethicist / Clergy

Brings moral and philosophical perspective to difficult decisions

P

Chairperson

Leads meetings, ensures due process, signs off on decisions

I

Independent / External Member

At least one member with no institutional affiliation, ensuring independence

Core Responsibilities of the Committee

Protect participants

Rights, safety, and wellbeing of all current and prospective participants are the top priority.

Review before approval

Evaluate protocol, consent documents, and recruitment materials before any research activity begins.

Monitor ongoing studies

Conduct continuing review at defined intervals, and review adverse event reports.

Ensure competence

Confirm the research team is qualified and facilities are adequate for the study.

Maintain documentation

Keep full records of submissions, decisions, and correspondence for audit and accountability.

Act with independence

Decisions must be free from institutional, financial, or political pressure.

The Submission & Approval Process

Possible outcomes: Approved • Approved with required modifications • Deferred pending clarification • Rejected

Protocol Development

Researcher prepares protocol, consent forms, and supporting documents

Submission

Complete application submitted to the committee with all required documents

Review

Committee evaluates scientific merit, risk–benefit, and consent process

Decision

Approved / Approved with modifications / Deferred / Rejected

Ongoing Monitoring

Continuing review, amendment approval, and adverse event reporting

What the Committee Reviews

Study Design Documents

- ✓ Full research protocol & scientific rationale
- ✓ Informed consent form and information sheet
- ✓ Investigator qualifications & CVs
- ✓ Recruitment materials & advertisements

Participant Protection Documents

- ✓ Data safety & monitoring plan
- ✓ Confidentiality & data protection measures
- ✓ Compensation and injury/insurance arrangements
- ✓ Conflict-of-interest declarations

Continuing Review & Monitoring

Committee oversight does not end at approval — it continues for the life of the study.

1	**Periodic Re-approval**	Most committees require review at least annually (or per local regulation) to confirm the study should continue.
2	**Amendment Review**	Any change to protocol, consent form, or investigators must be approved before implementation.
3	**Adverse Event Reporting**	Serious or unexpected adverse events must be reported promptly for safety review.
4	**Site Audits & Inspections**	Committees may audit records and sites to confirm the approved protocol is being followed.
5	**Study Closure Report**	A final report summarising outcomes and any deviations is submitted at study completion.

03

Informed Consent

Turning ethical principle into everyday clinical and research practice

What Is Informed Consent?

A voluntary, ongoing agreement to participate, given by a person who has been adequately informed and has the capacity to decide.

1

Disclosure

Relevant information is shared clearly and completely

2

Comprehension

The person genuinely understands what they are told

3

Voluntariness

The decision is free from coercion or undue influence

Essential Elements of a Valid Consent

Purpose

Why the study is being done and what it aims to find out

Procedures

What will happen, how long it takes, and what is expected of the participant

Risks & Discomforts

Reasonably foreseeable risks, side effects, or discomfort

Benefits

Expected benefits to the participant and/or to society

Alternatives

Any alternative procedures or treatments available

Confidentiality

How personal data and records will be protected

Voluntariness

Participation is voluntary; refusal involves no penalty

Right to Withdraw

Participant may withdraw at any time without losing entitled care

Contact Information

Who to contact with questions or in case of research-related injury

Consent Is a Process — Not Just a Form

The Signed Form

- Legal / documentary evidence that consent occurred
- A single point-in-time signature
- Cannot by itself guarantee understanding
- Reading level, length, and jargon can defeat its purpose

The Consent Process

- An ongoing dialogue, not a one-time event
- Information given verbally and in writing, with time to ask questions
- Comprehension actively checked (e.g., teach-back method)
- Consent can be revisited and withdrawn at any stage

Vulnerable Populations & Special Considerations

Extra safeguards apply when capacity, freedom, or power imbalances may compromise voluntary consent.

Children

Parent/guardian gives permission; child's assent sought when developmentally appropriate

Cognitively Impaired

Legally authorised representative consents; participant's own assent respected where possible

Pregnant Women

Special protections for maternal and fetal safety; risk–benefit carefully weighed

Prisoners

Safeguards against coercion given restricted freedom to decline

Students / Employees

Risk of subtle coercion by those in a position of authority over them

Emergency / Unconscious Patients

Deferred or surrogate consent procedures defined in advance and reviewed

Common Pitfalls That Undermine Consent

Therapeutic Misconception

Participants confuse research procedures with personalised clinical care, overestimating benefit to themselves

Consent Form Overload

Long, jargon-heavy documents that few participants actually read or understand

Coercion by Authority

A treating physician also acting as researcher can pressure patients to enrol

Financial Inducement

Payment large enough to cloud honest risk assessment, especially for low-income participants

Consent Once, Forgotten

Failing to re-confirm consent when the protocol changes or new risks emerge

Language & Literacy Barriers

Information not adapted to the participant's language or health literacy level

SUMMARY

Key Takeaways

1. Ethical research rests on 7 requirements — value, validity, fair selection, favorable risk–benefit, independent review, informed consent, and respect for participants
2. Ethical Review Committees provide independent, multidisciplinary oversight before, during, and after a study
3. Informed consent is an ongoing process of disclosure, comprehension, and voluntary choice — not a one-time signature
4. Vulnerable populations require additional safeguards to ensure genuine, uncoerced participation
5. As future clinicians, protecting participants is both a legal duty and a professional responsibility

Questions & Discussion

“Good clinical practice begins with respect for the person in front of you.”