

## Unit 4. Research Ethics

### Unit 4: Research Ethics

### Learning Outcomes

After studying this unit, you will be able to:

- Explain **why research ethics is essential** to good science and patient/community welfare.
- Describe the composition, roles, and workflows of **Institutional Human Ethics Committees (IHEC/IEC)** and **Institutional Animal Ethics Committees (IAEC)** in the Indian context.
- Apply the core ethical principles—**respect for persons/autonomy, beneficence, non-maleficence, and justice**—to design and review research.
- Practise sound **publication ethics**: authorship criteria, conflict-of-interest disclosure, plagiarism avoidance, trial registration, data sharing, and responsible reporting.

### 1) Need and Significance of Research Ethics

#### 1.1 Why Ethics Is Integral (Not Optional)

Ethics is about **protecting dignity, rights, safety, and well-being** of participants and communities while producing reliable knowledge. Unethical research:

- **Harms participants** (avoidable risk, breach of privacy, exploitation).
- **Corrupts evidence** (biased, irreproducible, or fabricated data).
- **Destroys trust** (patients and public withdraw support).
- **Wastes resources** (time, money, specimens).

Hence, **scientific validity itself is an ethical requirement**: a poorly designed study exposes people/animals to risk **without the prospect of valuable knowledge**.

#### 1.2 Four Cornerstones

##### 1. Respect for Persons / Autonomy

- Obtain **informed consent**: voluntary, competent, and adequately informed.
- Provide **comprehensible** information in local language; give time to decide; no coercion/undue influence.
- Permit **withdrawal** without penalty; describe alternatives and compensation for time/expenses.

##### 2. Beneficence

- Maximise **anticipated benefits** (clinical, social, scientific).
- Use trained staff, validated tools, and monitoring to enhance potential benefit.

##### 3. Non-maleficence

- Minimise **risk and burden**: sound dose ranges, safety labs, rescue protocols, stopping rules, DSMB where needed.
- Carefully justify placebo; maintain **standard of care** where required.

##### 4. Justice

- **Fair selection** of participants; avoid targeting vulnerable groups for convenience.
- **Equitable distribution** of burdens and benefits, including **post-trial access** when appropriate.

#### 1.3 Risk-Benefit Appraisal (Human Studies)

- **Minimal risk**: probability and magnitude no greater than daily life or routine exams. May be eligible for expedited review.
- **More than minimal risk**: requires full-board review, robust monitoring, and explicit justification.
- **Special populations** (children, pregnant women, persons with diminished autonomy, socially/economically



vulnerable): add safeguards, assent where applicable, legally acceptable representative consent, **audio-video consent** where mandated for defined clinical trials.

**Data protection:** limit access, de-identify datasets, secure storage, **data sharing** with governance (DUA/MTA), and clear data retention/archival plans.

## 1.4 Cultural Sensitivity and Integrative Care

In studies involving **Ayurveda/whole-system care**:

- Explain *diagnostic constructs* (e.g., *doṣa*, *agni*, *srotas*) and rationale in **plain language**.
- Disclose **herb-drug interaction** possibilities; ensure **quality-assured formulations** (GMP, standardisation, pharmaco-vigilance).
- Respect **dietary/religious** practices when prescribing *Pathya–Apathya*; avoid coercion.
- Where community beliefs are central, use **community engagement** and local advisory inputs.

## 2) Institutional Ethics Oversight

### 2.1 Institutional Human Ethics Committee (IHEC/IEC)

#### Mandate

Independent oversight of **biomedical and health research** involving humans (participants, data, or biological materials), ensuring **scientific merit**, **ethical conduct**, and **regulatory compliance** (e.g., national guidelines and clinical-trial rules). Student projects also need review if they involve human participants/data beyond routine educational activity.

#### Composition (typical, 7–15 members)

- **Medical/clinical experts** from relevant specialties.
  - **Basic scientist** and **statistician/epidemiologist**.
  - **Legal expert**.
  - **Social scientist/NGO representative/community lay person**.
  - **Ethicist/philosopher/theologian**.
  - **Member Secretary** (organises reviews); **Chairperson** (preferably external).
- Diversity in **gender**, **discipline**, and **independence** is essential. A valid meeting requires a **quorum** including at least **one non-scientific** and **one independent/external** member.

#### Core Functions

- **Scientific-ethical review:** protocol, tools, consent forms (all versions and languages), recruitment, compensation for time/travel, risk-benefit, data protection, publication plan.
- **Continuing review:** annual/periodic; review of deviations, amendments, serious adverse events (SAEs).
- **Site monitoring** when warranted.
- **Record-keeping** and archiving; SOP maintenance; training of members/investigators.

#### Review Pathways

- **Exemption:** anonymised educational research, publicly available data—**no interaction** and **minimal risk**; still submit for exemption determination.
- **Expedited:** minimal-risk studies (e.g., validated questionnaires, stored anonymised specimens without identifiers).
- **Full-board:** more-than-minimal risk; vulnerable populations; clinical trials of new interventions.

#### Consent Essentials (Human)

- Purpose, procedures, **duration**, and **randomisation/placebo** if any.

- Risks/benefits; **compensation** for study-related injury as per national rules; free medical management for study-related harm where mandated.
- Privacy/confidentiality, data sharing, future use of samples (with options: specific, broad, or refusal).
- **Voluntariness and withdrawal**, contact details for PI and IHEC, and grievance redressal.
- **Language**: simple, local translation verified. **AV recording** where required by regulation.
- **Assent** for minors + LAR consent; safeguards for individuals with impaired consent capacity.

### Registration & Transparency (Human)

- **Prospective trial registration** (e.g., national clinical trials registry) **before** first participant.
- Public disclosure of protocol synopsis where applicable; inclusion of registration number in manuscripts.
- Reporting **SAEs** within stipulated timelines to the IHEC and regulator; **compensation** determination as per national formulae.

## 2.2 Institutional Animal Ethics Committee (IAEC)

### Mandate

Ethical oversight of **animal research and teaching**, ensuring scientific justification, humane care, and compliance with national rules for animal facilities and experiments.

### Composition (typical)

- **Chairperson** (preferably external).
  - **Biological scientist(s)** and **two scientists** experienced in animal work.
  - **Veterinarian** (with laboratory animal care expertise).
  - **Scientist-in-charge of animal facility** (Member Secretary).
  - **Socially aware/lay person**.
  - **Nominee** of the national oversight body/regulator, where applicable.
- A registered **animal house** and properly trained staff are prerequisites.

### Ethical Framework: the 3Rs

1. **Replacement**: use non-animal alternatives if they can answer the question (cell culture, in-silico, organ-on-chip, validated simulations).
2. **Reduction**: minimum number of animals compatible with **statistical power**; appropriate experimental design to avoid repeat experiments.
3. **Refinement**: minimise pain/distress—**anaesthesia, analgesia**, humane endpoints, skilled techniques, enriched housing, post-procedure care.

### Severity & Justification

- Categorise procedures by **severity** (no-recovery/mild/moderate/severe).
- Avoid or strongly justify **severe** procedures; propose **humane endpoints** and clear **monitoring checklists**.
- **Euthanasia**: use approved methods; document justification and technique; trained personnel only.

### What IAEC Reviews

- Scientific rationale and **non-duplication**.
  - **Species/strain** choice and **sample size** calculation.
  - **Procedural details** (surgery, injections, blood collection), **pain management, post-operative care**.
  - **Personnel training/competence** and facility readiness.
  - **Record-keeping**: animal acquisition, consent of breeder/supplier, morbidity/mortality logs, disposal.
- Some categories (e.g., **large animals**, primates, or higher-severity protocols) may require **additional national-level approval**.

## 3) Publication Ethics

### 3.1 Authorship and Contributorship

Use the **ICMJE authorship criteria** (all four must be met):

1. Substantial contribution to conception/design or data acquisition/analysis/interpretation;
2. Drafting or critical revision for important intellectual content;
3. Final approval of the version to be published;
4. Accountability for all aspects of the work.

Avoid:

- **Guest authorship** (adding names without contribution),
- **Gift authorship** (senior names for favour),
- **Ghost authorship** (uncredited writers).

Best practice: include **CRediT taxonomy** (Conceptualization, Methodology, Investigation, Data curation, Formal analysis, Writing-original draft, Writing-review & editing, Supervision, Funding acquisition, etc.) so contributions are transparent.

### 3.2 Conflicts of Interest (COI)

Disclose **financial** (grants, fees, equity), **intellectual**, **personal**, and **institutional** interests for **all authors** and, where applicable, for reviewers and editors. Manage COI by transparency, analytic independence, and, if needed, **third-party analysis** or **independent DSMB**.

### 3.3 Integrity of the Record

- **Trial registration** and protocol availability; report **registration number** in the abstract/manuscript.
- Follow reporting standards (**CONSORT**, **STROBE**, **PRISMA**, **CARE**, **ARRIVE** for animal studies).
- **No fabrication or falsification**; retain raw data for audit; document all analyses.
- **Image integrity**: do not alter scientific meaning; disclose adjustments (brightness/contrast uniformly). Keep original files.
- **Plagiarism**: paraphrase with attribution; quote sparingly with citation; check overlap before submission.
- **Redundant publication/salami slicing**: do not publish overlapping datasets as separate “new” papers; if necessary, cross-reference and justify.
- **Duplicate submission**: submit to only one journal at a time.
- **Corrections/Retractions**: promptly correct honest errors; cooperate in retractions for serious misconduct.

### 3.4 Choosing the Right Journal

- Aim for journals that practise **editorial independence**, follow **COPE** guidance, and have **transparent APC policies**.
- Prefer recognised indexing/whitelists; avoid **predatory journals** that promise unrealistic timelines and lack genuine peer review.

### 3.5 Data, Code, and Materials

- Provide **Data Availability Statements**. Share **de-identified datasets** and **analysis code** when possible under appropriate licences and approvals.
- For **biological materials** (herbal extracts, strains), use **Material Transfer Agreements** (MTA).

### 3.6 Patient Privacy and Case Reports

- Obtain **specific patient consent** for identifiable images/cases; remove identifiers; blur faces/marks when required.

- For community-derived knowledge, acknowledge **benefit-sharing** and community permissions where relevant.

### 3.7 Responsible Use of Generative AI

- **AI tools cannot be listed as authors.**
- If used for **language editing or figure assistance**, **disclose** the tool and **verify** factual accuracy; do not upload sensitive or confidential data to public tools.
- The **intellectual responsibility** remains with the authors.

## 4) Practical Checklists

### 4.1 IHEC Submission Checklist (Human)

- Final protocol with background, objectives, design, sample size, analysis plan.
- Participant materials: **ICF** (all languages), **PIS**, recruitment posters/scripts.
- Risk mitigation: safety plan, stopping rules, DSMB (if applicable).
- Data: CRFs, confidentiality plan, storage/retention, sharing plan.
- **Registration plan** for eligible trials.
- Investigator CVs, GCP training, site facilities letter.

### 4.2 IAEC Submission Checklist (Animal)

- Scientific justification; **3Rs** statement.
- Species, numbers with **power justification**.
- Procedures with anaesthesia/analgesia, post-op care, humane endpoints.
- Personnel competency; facility SOPs and registration.
- Disposal and euthanasia method.
- Adverse event reporting plan.

### 4.3 Manuscript Ethics Checklist

- Authorship meets criteria; **CRedit** attached.
- **COI** disclosures completed.
- Trial/Study registered (if applicable) and number reported.
- Reporting guideline checklist uploaded.
- Plagiarism check done; permissions for reused figures obtained.
- Data/code sharing statement finalised.

## 5) Take-Home Messages

- **Ethics and science are inseparable:** validity, transparency, and participant welfare go together.
- **IHEC/IEC** and **IAEC** offer **independent, multidisciplinary** oversight—engage early and follow SOPs throughout the study lifecycle.
- **Publication ethics** protects the scientific record, your reputation, and—most importantly—patients and communities who trust us.

## Assessment

### A. Multiple-Choice Questions (MCQs)

1. Which statement best captures the ethical status of **scientific validity**?



- A) It is desirable but not an ethical requirement.
- B) It is an ethical requirement because invalid studies waste risk.
- C) It is relevant only to regulatory trials.
- D) It applies to animal research but not human.

**Answer: B**

2. A minimal-risk survey using anonymised questionnaires among interns may be eligible for:
- A) Exemption or expedited review (as per IHEC SOPs).
  - B) Full-board review only.
  - C) No review at all.
  - D) IAEC review.

**Answer: A**

3. The ethical principle chiefly concerned with **fair distribution of burdens and benefits** is:
- A) Autonomy
  - B) Beneficence
  - C) Justice
  - D) Fidelity

**Answer: C**

4. The **3Rs** in animal ethics stand for:
- A) Registration, Reporting, Randomisation
  - B) Replacement, Reduction, Refinement
  - C) Repetition, Replication, Reuse
  - D) Restriction, Regulation, Rejection

**Answer: B**

5. A valid IHEC meeting generally requires a **quorum** that includes at least:
- A) Only clinicians
  - B) One non-scientific and one independent/external member
  - C) All PIs on the agenda
  - D) Only the Chair and Member Secretary

**Answer: B**

6. **Guest authorship** refers to:
- A) Adding an author who made no substantial contribution
  - B) Omitting an author who contributed
  - C) A professional language editor listed as an author
  - D) A visiting researcher contributing analysis

**Answer: A**

7. Which is **not** good practice in publication ethics?
- A) Prospective trial registration and citing the number
  - B) Using CRediT to declare contributions
  - C) Submitting the same manuscript to two journals simultaneously
  - D) Providing data availability statements

**Answer: C**

8. For **vulnerable participants**, consent safeguards most likely include:
- A) No written information to avoid confusion
  - B) Audio-video consent and LAR consent, with assent where appropriate
  - C) Waiver of consent by default
  - D) Only telephone consent

**Answer: B**

9. In IAEC review, **severe** procedures:
- A) Are acceptable without extra justification
  - B) Should be avoided or heavily justified with humane endpoints
  - C) Do not need analgesia
  - D) Need no monitoring

**Answer: B**

10. **Image manipulation** in a submitted figure is acceptable when:
- A) It enhances contrast in selected regions only



- B) It changes the meaning but looks nicer
- C) It uniformly adjusts brightness/contrast without altering interpretation and is disclosed
- D) It removes outliers

**Answer: C**

## **B. Short-Answer Questions (SAQs)**

1. List and briefly explain the four core ethical principles that guide human research.
2. What are the main differences between **exemption**, **expedited**, and **full-board** review? Give one example each.
3. Outline the **3Rs** with one concrete example for each in an animal study.
4. Define **authorship** according to ICMJE and name two forms of unethical authorship.
5. What must a **participant information sheet (PIS)** and **informed consent form (ICF)** contain at minimum?

## **C. Long-Answer Questions (LAQs)**

1. **Designing an ethically sound integrative trial:** You plan a pragmatic RCT adding a whole-system Ayurvedic package to usual osteoarthritis care in a district hospital. Describe your ethical strategy for consent (language, AV), risk mitigation, monitoring/DSMB, compensation for injury, data privacy, and post-trial access.
2. **Institutional oversight end-to-end:** Map the complete lifecycle of a human study from concept to closure through IHEC processes—initial review, continuing review, amendments, SAE reporting, deviations, monitoring visits, data archiving, and final report—highlighting investigator responsibilities.

## **D. Case Vignette (Applied Ethics)**

A postgraduate proposes a study on **Takra-based diet counselling** versus usual diet advice for functional dyspepsia. Recruitment is from the OPD; randomisation is by sealed envelopes; participants receive a travel reimbursement.

### **Tasks:**

- a) Identify **two ethical strengths** and **two concerns**.
- b) State whether **trial registration** is required and why.
- c) Draft **two sentences** (in plain language) to include in the ICF about voluntary participation and withdrawal.

End of Unit 4.