Unit 4. Research Ethics

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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.

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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.

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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.

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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.

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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.