

UNIT – 3

1. Ethics-Ethical Issues

Ethics in research refers to the principles and standards that guide researchers to conduct their work responsibly, honestly, and respectfully, especially when it involves human or animal participants. Ethical issues in research methodology arise at all stages — from planning and conducting research to reporting and publishing results.

a. What is Research Ethics?

Research ethics involves applying fundamental ethical principles to scientific research activities. These principles include:

- **Integrity** – Honesty and consistency in research.
- **Objectivity** – Avoiding bias in methodology, data analysis, and interpretation.
- **Respect for persons** – Acknowledging autonomy and protecting those with diminished autonomy.
- **Beneficence** – Maximizing benefits and minimizing harm.
- **Justice** – Fair distribution of research benefits and burdens.

b. Types of Ethical Considerations

i. Informed Consent

- a. Informed consent ensures that participants are fully aware of the research purpose, methods, potential risks, and benefits. Participants must voluntarily agree to participate without coercion or undue influence.
- b. **Example:** In a medical study, participants are given a document explaining the study's purpose, procedures, and risks, and must sign it to confirm they understand and agree to participate.

ii. Confidentiality and Privacy

- a. Confidentiality involves protecting participants' data and privacy, ensuring that their personal information is not disclosed without permission. Researchers are responsible for safeguarding data and maintaining anonymity.
- b. **Example:** A survey on mental health should not reveal any identifying information about participants, and data should be stored securely to protect privacy.

iii. Minimization of Harm

- a. Minimizing harm requires researchers to reduce any risks to participants. Harm can be physical, psychological, social, or emotional, and researchers must design studies that avoid unnecessary distress.
- b. **Example:** In an experiment involving stressful tasks, researchers should monitor participants' stress levels and allow them to withdraw if discomfort arises.

iv. **Conflict of Interest**

- a. Conflict of interest occurs when researchers or practitioners have personal or financial interests that could affect their objectivity. Disclosing any potential conflicts is critical to maintaining transparency and credibility.
- b. **Example:** A pharmaceutical researcher with stock in a drug company must disclose this relationship to avoid bias when reporting drug effectiveness.

v. **Honesty and Integrity**

- a. Honesty and integrity in research involve accurately reporting findings, avoiding fabrication or falsification of data, and acknowledging any limitations of the study. Plagiarism is also a violation of research integrity.
- b. **Example:** A researcher should report all data, even if results do not support their hypothesis, to ensure truthful representation of findings.

vi. **Respect for Vulnerable Populations**

- a. Researchers must take special care when working with vulnerable populations, such as children, elderly individuals, or people with disabilities, ensuring extra protections and sensitive handling of data.
- b. **Example:** When conducting interviews with children, researchers must have parental consent and ensure questions are age-appropriate.

2. **Ethical Committees (Human & Animal)**

Ethical committees, also known as **Institutional Review Boards (IRBs)** for human research or **Institutional Animal Ethics Committees (IAECs)** for animal research, play

a crucial role in **ensuring that research is conducted ethically, safely, and legally**. These committees are responsible for reviewing research proposals before the work begins and monitoring ongoing studies to protect the welfare of participants and uphold ethical standards.

A. Human Research Ethics Committees (HREC / IRB)

Definition:

A **Human Research Ethics Committee (HREC)** or **Institutional Review Board (IRB)** is a formally designated body that reviews, monitors, and approves research involving human participants.

Functions:

- **Review research proposals** involving human subjects.
- Ensure **informed consent** is properly obtained.
- Assess **risk-benefit ratio** (minimizing harm and maximizing benefit).
- Protect **privacy and confidentiality** of participants.
- Monitor **ongoing research** and compliance with ethical standards.

Composition:

Typically includes:

- Scientists and medical experts
- Legal experts
- Ethicists/philosophers
- Laypersons (to represent public interest)
- Social scientists

Ethical Guidelines Followed:

- **Declaration of Helsinki**
 - **Belmont Report**
 - **CIOMS Guidelines** (Council for International Organizations of Medical Sciences)
 - **ICMR Guidelines** (India-specific)
 - Local/national laws and regulations
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B. Animal Ethics Committees (IAEC)

Definition:

An **Institutional Animal Ethics Committee (IAEC)** is responsible for reviewing and approving protocols for research involving animals to ensure ethical and humane treatment.

Functions:

- Ensure **minimal pain or distress** to animals.
- Review the **justification for animal use**.
- Approve **number and species** of animals used.
- Ensure **housing, feeding, and care** meet ethical standards.
- Approve methods of **euthanasia or sacrifice**, if applicable.

Composition (as per CPCSEA Guidelines - India):

- Biological scientist
- Veterinarian
- Scientist from a different field
- Non-scientific socially aware member
- CPCSEA nominee (Committee for the Purpose of Control and Supervision of Experiments on Animals)
- Institutional head
- Member secretary

Ethical Guidelines Followed:

- **CPCSEA Guidelines (India)**
- **OECD Guidelines**
- **ARRIVE Guidelines** (for reporting animal research)
- **3Rs Principle:**
 - **Replacement** (use alternatives to animals)
 - **Reduction** (use minimum number of animals)
 - **Refinement** (minimize pain and improve welfare)

C. Importance of Ethical Committees

- **Protects subjects (human and animal)** from unethical treatment.
- Ensures **scientific integrity** of research.
- Promotes **public trust** in research institutions.
- Enforces **legal compliance** with national and international laws.
- Encourages **accountability and transparency** in research practice.

3. IPR- Intellectual Property Rights and Patent Law

A. What is Intellectual Property (IP)?

Intellectual Property (IP) refers to **creations of the mind**, such as inventions, literary and artistic works, designs, symbols, names, and images used in commerce.

Intellectual Property Rights (IPR) are the **legal rights** granted to creators to protect their creations.

B. Types of Intellectual Property Rights (IPR)

Type of IPR	Description	Example
Patent	Protects new inventions (products or processes)	A new drug formula
Copyright	Protects original literary and artistic works	Books, music, films

Type of IPR	Description	Example
Trademark	Protects brand names, logos, slogans	Nike® logo, McDonald's "I'm Lovin' It"
Design Rights	Protect the aesthetic aspects of a product	Shape of a bottle or furniture design
Trade Secrets	Protects confidential business information	Coca-Cola formula
Geographical Indications (GI)	Protects products with a specific geographical origin	Darjeeling tea, Basmati rice

C. What is a Patent?

A **patent** is an exclusive right granted for an **invention**, which must be:

- **Novel (new)** – Not publicly disclosed anywhere in the world.
- **Inventive (non-obvious)** – Not obvious to someone skilled in the field.
- **Useful (industrially applicable)** – Capable of being used in industry.

Duration:

- Typically **20 years** from the filing date.
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D. Patent Law

Patent law is a **branch of IPR law** that governs the rules and procedures for **obtaining, enforcing, and protecting patents**.

Key Elements of Patent Law:

- **Filing Process** – Involves submitting an application to the patent office.
- **Examination** – Patent examiners evaluate the novelty and utility.
- **Grant** – If approved, the patent is granted with exclusive rights.
- **Enforcement** – Patent holders can **sue for infringement**.
- **Renewal and Expiry** – Patents can lapse if not renewed with required fees.

Not Patentable (in many countries):

- Scientific theories or mathematical methods
 - Abstract ideas or mental acts
 - Discoveries of natural substances
 - Methods of medical treatment (in some countries)
 - Software algorithms (depending on jurisdiction)
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E. Importance of IPR and Patent Law

- **Encourages innovation** by rewarding inventors.
- **Protects the investment** in R&D and creativity.

- Promotes **economic growth and competitiveness**.
 - Ensures **recognition and financial benefit** for creators.
 - Facilitates **technology transfer** and public disclosure of inventions.
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F. International Agreements on IPR

- **TRIPS (Trade-Related Aspects of Intellectual Property Rights)** – WTO agreement that sets minimum standards for IPR.
- **Paris Convention** – Protection of industrial property across member countries.
- **Patent Cooperation Treaty (PCT)** – Facilitates international patent filing.

4. Commercialization, Copy Right, Royalty, Trade Related Aspects of Intellectual Property Rights (TRIPS)

A. Commercialization of Intellectual Property (IP)

Commercialization is the process of **bringing intellectual property (IP) to the market** to generate profit or value. It involves turning innovations, research outcomes, or creative works into **commercial products, services, or licenses**.

Ways to Commercialize IP:

- **Licensing** – Granting permission to others to use the IP for a fee.
- **Assignment** – Selling the ownership rights to another party.
- **Joint Ventures/Partnerships** – Collaborating to market IP-based products.
- **Startups/Spin-offs** – Creating new businesses based on the IP.

Importance:

- Promotes **innovation and entrepreneurship**.
 - Generates **revenue** through sales or royalties.
 - Encourages **investment** in research and development.
 - Contributes to **economic development**.
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B. Copyright

Copyright is a legal right that gives the **creator of original works** (literary, artistic, musical, etc.) the exclusive right to use and distribute their work.

Covers:

- Books, articles, software
- Music, lyrics, audio
- Films, videos, plays
- Paintings, photographs, designs

Duration:

- Usually **60 years after the author's death** (varies by country).

Rights Under Copyright:

- **Reproduction right**
- **Distribution right**

- **Public performance**
- **Moral rights** (e.g., right to attribution)

Infringement can lead to legal action, fines, or imprisonment.

C. Royalty

A **royalty** is a **payment made to the owner of IP** for the use of their rights by others. It's usually a **percentage of revenue** generated from the use of the IP.

Examples:

- A publisher pays an author royalties on book sales.
- A company pays a software developer for using their code.
- A musician earns royalties from streaming services.

Types:

- **Fixed royalties** (fixed fee)
 - **Percentage-based royalties** (based on profit/sales)
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D. TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights)

Definition:

TRIPS is an **international legal agreement** between all member nations of the **World Trade Organization (WTO)** that sets **minimum standards** for IP regulation globally.

Came into effect: 1995

Key Features:

- **Covers all forms of IP:** patents, copyrights, trademarks, trade secrets, GIs, etc.
- **Requires:**
 - **Minimum protection standards**
 - **Effective enforcement mechanisms**
 - **Non-discriminatory treatment** (foreign and domestic IP holders)

Impact on Developing Countries:

- Requires strengthening IP laws.
 - Controversial in public health (e.g., access to affordable medicines).
 - Can stimulate technology transfer if implemented properly.
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E. Relationship Between These Concepts

Concept	Role in IP Management
Commercialization	Turns IP into products, services, or income
Copyright	Protects creative expressions legally
Royalty	Income from licensed IP usage
TRIPS	International framework for IP protection

5. Scholarly Publishing- IMRAD Concept and Design of Research Paper

A. What is Scholarly Publishing?

Scholarly publishing refers to the **dissemination of academic research** through journals, conferences, or online platforms. It allows researchers to:

- Share findings with the scientific community
- Gain recognition
- Contribute to knowledge advancement
- Fulfill academic or funding requirements

B. IMRAD Structure of a Research Paper

The **IMRAD** format is a standard structure used in scholarly writing, especially in **scientific and technical fields**. It stands for:

Section	Purpose
I – Introduction	<p>Presents background, problem statement, objectives, and hypothesis</p> <p>Your introduction would typically include some variation of the following:</p> <ul style="list-style-type: none">• Statement of the topic you are about to address• Current state of the field of understanding (often, we call this a literature review and it may even merit having its own section)• Problem or gap in knowledge (what don't we know yet or need to know? what does the field still need to understand? what's been left out of previous research? is this a new issue that needs some direction?)• Forecast statement that explains, very briefly, what the rest of the paper will entail, including a possible quick explanation of the type of research that needs to be conducted
M – Methods	<p>Describes how the research was conducted (design, materials, procedures)</p> <p>If your research methods are sound, your paper holds a lot more weight. A few tips to make your methods section work well:</p> <ul style="list-style-type: none">• Separate each type of research you conducted (interviews, focus groups, experiments, etc.) into sub-

Section	Purpose
	<p>sections and only discuss one research method in each sub-section (for clarity and organization, it's important to not talk about multiple methods at once)</p> <ul style="list-style-type: none"> • Be very detailed about your process. If you interviewed people, for example, we need to know how many people you interviewed, what you asked them, what you hoped to learn by interviewing them, why chose to interview over other methods, why you interviewed those people specifically (including providing they demographic information if it's relevant), and so forth. For other types of data collection, we need to know what your methods were—how long you observed; how frequently you tested; how you coded qualitative data; and so forth.
R – Results	<p>Shows the outcomes of the study using data, tables, graphs, etc. The results section is critical for your audience to understand what the research showed. Use this section to show tables, charts, graphs, quotes, etc. from your research. At this point, you are building your reader towards drawn conclusions, but you are not yet providing a full analysis. You're simply showing what the data says. Follow the same order as the Methods section—if you put interviews first, then focus groups second, do the same in this section.</p>
A – And	<p>[Linking word, not a separate section]</p>
D – Discussion	<p>Interprets results, compares with previous studies, explains implications.</p> <p>Finally, you conclude this paper by suggesting what new knowledge this provides to the field. You'll often want to note the limitations of your study and what further research still needs to be done. If something alarming or important was</p>

Section	Purpose
	discovered, this is where you highlight that information. If you use the IMRaD format to write other types of papers (like a recommendation report or a plan), this is where you put the recommendations or the detailed plan.

C. Components of a Research Paper (Design/Layout)

- **Title**
 - Clear, concise, and reflects the content of the paper
- **Abstract**
 - A short summary (150–300 words) of the aim, method, results, and conclusion
- **Keywords**
 - 4–6 keywords to help index the paper in search databases
- **Introduction**
 - Context and background
 - Research gap
 - Objectives/hypothesis
- **Literature Review** (*Sometimes separate, sometimes within Introduction*)
 - Overview of existing research
 - Identification of gaps
- **Materials and Methods**
 - Detailed enough to allow replication
 - Description of tools, data collection, and analysis techniques
- **Results**
 - Objective reporting of findings
 - Use of visuals: tables, graphs, charts
- **Discussion**
 - Interpretation and implications
 - Comparison with previous findings
 - Limitations and strengths
- **Conclusion**
 - Summary of key findings
 - Future scope/recommendations
- **References**
 - Cited works using a standard citation style (APA, MLA, IEEE, etc.)
- **Acknowledgments** (*optional*)
 - Credits to contributors or funders

- **Appendices** (*if required*)
 - Additional material like questionnaires, formulas, or detailed data

D. Importance of IMRAD in Scholarly Publishing

- **Consistency** – Enables easier reading and understanding
- **Clarity** – Helps readers identify relevant sections quickly
- **Standardization** – Supports peer review and indexing
- **Reproducibility** – Ensures research methods are clearly described

6. Citation and Acknowledgement, Plagiarism, Reproducibility and Accountability

A. Citation and Acknowledgement

1.1.1. Citation

A **citation** is a formal reference to the work of others that you use in your research. It gives **credit to the original author** and allows readers to locate the sources you used.

Purpose:

- To **avoid plagiarism**
- To **support your arguments** with established knowledge
- To show the **depth of your research**
- To give **credit to original authors**

Common Citation Styles:

- **APA (American Psychological Association)** – Social sciences
- **MLA (Modern Language Association)** – Humanities
- **IEEE** – Engineering and technical papers
- **Chicago/Turabian** – History, general writing

1.1.2. Acknowledgement

The **Acknowledgement section** is where authors thank individuals or institutions that helped in the research but are not co-authors.

May include:

- Funding agencies or sponsors
- Supervisors, mentors, or colleagues
- Technical staff or institutions
- Family or emotional supporters (informally)

B. Plagiarism

Definition:

Plagiarism is the unethical act of **using someone else's work, ideas, or words** without proper attribution.

Plagiarism can be intentional or unintentional. We should have the knowledge of what can be called plagiarized content and what not. Following are the key points to understand what can be called as plagiarism:

- If we use another person's work under our name.
- If we copy other's ideas and words and don't give them the credit.
- If we download copyrighted images or music and present them as our own.
- If we copy maximum words and modify them so that we can cleverly use them under our own name.
- If we use someone else's copyrighted music or video for our own music cover or video.
- If we recreate an image, video, music, article, etc in such a manner that it is quite similar to the original one.

Types of Plagiarism:

- **Direct Plagiarism** – Copying text word-for-word without citation.
 - Complete Plagiarism is the most extreme form of plagiarism. In this plagiarism, a person completely copies someone else's work such as a research paper, article, image, etc, and represents it as their own work. This form of plagiarism is similar to identity theft or stealing.
- **Self-Plagiarism** – Reusing one's own previous work without acknowledgment.
 - This kind of plagiarism is the duplication of a person's own work. It is also known as auto plagiarism. It occurs when a person copies some words of his own published work and uses the same for another work. This form of plagiarism is commonly observed in research journals. Researchers may make re-use of their research work for another research work, however, the percentage of re-usage must be according to those set by the publishing journals if they allow them to do so.
- **Mosaic Plagiarism** – Mixing copied phrases into original text without citation.
- **Accidental Plagiarism** – Failing to cite sources properly due to ignorance or oversight.
 - This kind of plagiarism mostly occurs due to a lack of knowledge. If we don't know how to paraphrase, cite and quote a research work we leave the work as it is and it results in accidental plagiarism.

Consequences:

- Academic penalties (failures, suspension)
- Damage to reputation and credibility
- Legal issues in extreme cases

How to avoid plagiarism?

There are certain steps we can follow in order to avoid plagiarism.

- Always give credit to the person whose work you are including in your own work. Make use of double quotations to prevent verbatim.
- Build your own ideas and thoughts and use them in your work. Do not copy another person's ideas or work. Develop yourself and work on yourself so that you can enhance your thought process. Increase the domain of your knowledge.
- Make use of paraphrasing. Paraphrasing means the representation of an idea or thought in our own words in such a manner that the original essence of that idea remains the same. But we should also do paraphrasing in such a manner that it does not convert to plagiarism.
- Always provide correct references in your research paper or article.
- Learn how to cite your articles, provide references, use double quotations, etc. You should know how to write a scholarly article or book or research paper before you begin writing.
- If you are using someone else's videos, images, or audios in your own video, etc always ask them first, and even after that provide them the credit for the same.

C. Reproducibility

Definition:

Reproducibility means that **other researchers can repeat your experiment** and get the same results, based on your description of the methods and data.

Importance:

- Ensures **validity** and **reliability** of scientific claims
- Builds **trust** in research
- Promotes **transparency** in the scientific process

Requirements:

- Clear **documentation** of methods and procedures
- Sharing of **data, code, and tools**
- Use of **standardized protocols**

D. Accountability

Definition:

Accountability in research means taking **responsibility for the integrity and honesty** of your work and behavior during the research process.

Principles of Research Accountability:

- **Honesty** – In reporting data and results
- **Objectivity** – Avoiding bias
- **Integrity** – Following ethical guidelines
- **Transparency** – Clear communication and openness

- **Responsibility** – Toward subjects, society, and the research community