BIOETHICS ,IPR & RESEARCH METHODOLOGY

UNIT 1

Professional ethics and codes of conduct

Professional ethics are principles that govern the behaviour of a person or group in a business environment. Like values, professional ethics provide rules on how a person should act towards other people and institutions in such an environment.

- Unlike values, professional ethics are often codified as a set of rules, which a particular group of people use.
- This means that all those in a particular group will use the same professional ethics, even though their values may be unique to each person.
- The code is an example of a codified set of professional ethics for those who choose to enter the immigration advice profession.

Ethical principles

Ethical principles underpin all professional codes of conduct. Ethical principles may differ depending on the profession; for example, professional ethics that relate to medical practitioners will differ from those that relate to lawyers or real estate agents.

However, there are some universal ethical principles that apply across all professions, including:

- Honesty
- Trustworthiness
- Loyalty
- Respect for others
- Adherence to the law
- Doing good and avoiding harm to others
- Accountability.

Codes of conduct

- Professional codes of conduct draw on these professional ethical principles as the basis for prescribing required standards of behaviour for members of a profession.
- They also seek to set out the expectations that the profession and society have of its members.
- The intention of codes of conduct is to provide guidelines for the minimum standard of appropriate behaviour in a professional context.
- Codes of conduct sit alongside the general law of the land and the personal values of members of the profession.
- The primary value of a professional code of conduct is not as a checklist for disciplining non-conforming members, although breaches of a code of conduct usually do carry a professional disciplinary consequence.
- Rather, its primary value is to act as a prompt sheet for the promotion of ethical decision-making by members of that profession.

Professional codes of conduct provide benefits to:

- The public, as they build confidence in the profession's trustworthiness
- Clients, as they provide greater transparency and certainty about how their affairs will be handled
- Members of the profession, as they provide a supporting framework for resisting pressure to act inappropriately, and for making acceptable decisions in what may be 'grey areas'
- The profession as a whole, as they provide a common understanding of acceptable practice which builds collegiality and allows for fairer disciplinary procedures
- Others dealing with the profession, as the profession will be seen as more reliable and easier to deal with.

Other contributors to professional ethics

Fiduciary duties

When an adviser agrees to assist a client, they agree to take on a level of responsibility for that person and their immigration matter. The client becomes dependent on the adviser in relation to that assistance. This is a fiduciary relationship between the fiduciary (the adviser) and a principal (the client). Even without a code this fiduciary relationship means the adviser has certain obligations to their client.

Contractual obligations

When an adviser enters into a contract (or written agreement) with a client this creates legally binding obligations to perform the terms of the contract in a particular way. This includes a duty to act with diligence, due care and skill, and also implies obligations such as confidentiality and honesty, even if they are not specifically set out in the contract.

Many ethical issues are likely to stem from advisers' relationships with clients. Most of these can be overcome by having clear terms in a written agreement about how certain matters will be dealt with, such as the sharing of confidential information, the use of interpreters, refunds and invoicing. More information on written agreements can be found in the **code of conduct toolkit**.

Other laws

As well as new zealand immigration legislation, advisers should also be aware of other relevant laws that seek to regulate how service providers must behave. In new zealand this could include the consumer guarantees act 1993. Advisers operating outside of new zealand should make sure that they are familiar with any equivalent legislation that governs the behaviour of service providers there.

Laboratory accreditation

Submitting to a laboratory accreditation program involves the assessment of a laboratory by a third party assessor, who is a qualified member of an accreditation service. Typically, accrediting bodies are non-profit organizations, such as the joint commission international or ilac.

Accreditation is generally a voluntary process, the aim of which is to verify that certain types of facilities are implementing an appropriate quality management operation and are properly performing certain calibration parameters and test methods, such as iso and astm test methods.

The only lab accreditation required by the food and drug administration (fda) is the laboratory accreditation for analyses of foods (laaf). The epa requires that labs become certified to analyze drinking water samples. This requires a specific training and certification program and is unrelated to accreditation. All accreditation organizations have national standards, while some also have international standards.

The type of accreditation a laboratory applies for will depend on the type of research or testing they are involved in and the materials they use. In this article, we will explain the requirements for laboratory accreditation and outline some examples of different types of accreditation.

Trying to streamline the workflow and processes of your lab? Try lab automation *with a* lims *from genemod to take the next step in your lab's efficiency.*

General requirements of laboratory accreditation

In order to achieve accreditation, a lab has to show that it has a quality management system that meets certain requirements. It must also be able to show technical competence, in that it meets the required measurements for accuracy and traceability for its type of calibrations or testing. This is known as the scope of accreditation. Once a lab has been accredited, it will receive a certificate indicating that it has met the specified requirements.

General requirements for lab accreditation include the following aspects:

- Legal and contractual matters
- Certification agreements
- Use of certificates and license
- Non-discriminatory conditions
- Remarks of impartiality
- Confidentiality agreements

Laboratory accreditation is a way to promote and implement high-quality lab testing and reduce errors. Accreditation also underlines the credibility of services and results delivered by the laboratory by showing that it is compliant with rigorous quality and safety standards.

Laboratory accreditation process

There are several stages to the accreditation process. These are:

- *Assessment*: This stage involves the measurement of key performance indicators (kpis) such as staff competence, quality training, test compliance, the integrity of reporting results, quality in communication with users and/or patients, timeliness, and quality assurance.
- *Auditing*: A laboratory must document its management system to show that it is in compliance with the requirements of the accreditation standards. Lab managers should check that all procedures and activities throughout the lab are being implemented correctly by means of an internal audit.

If any discrepancies are revealed, lab managers should adjust these as necessary before submitting an application for accreditation.

- *Selection of accrediting body*: The accreditation must be performed by a professional organization that has the right to assess laboratory standards.
- *Submitting the application*: Once the above steps are completed, the lab can apply.

Types of laboratory accreditations

There are different types of lab accreditation for just about every type of laboratory. The form of accreditation a lab is given is dependent upon the materials and experimental methods the lab uses. Here are some examples of specific types of accreditation.

Iso 15189 and clia

This accreditation is specifically for clinical testing laboratories or medical laboratories. It has the following requirements:

- *Management system requirements*: Internal audits and reviews of management to show that the lab meets the qms. Focus is placed on risk management, advisory services, document control, and ongoing improvement.

- *Technical requirements*: An assessment of personnel training, education, and competence. It also includes an evaluation of lab equipment, testing processes, reagents and supplies, lab information management, and environmental conditions.

Iso 20387

This accreditation is specifically for biobanking. It has the following requirements:

- *Resource requirements*: An assessment of personnel qualifications, training, competence, laboratory environment, tests, services, products provided, and equipment.
- *Process requirements:* An evaluation of collection, reception, distribution, transport of biological materials and associated data, quality control, and validation of methods.
- *Quality management systems requirements*: An assessment of methods, documentation, and risk assessment.

Iso 17034

This accreditation is specifically for reference materials producers. It has the following requirements:

- *Structural requirements*: An assessment of personnel duties and responsibilities, and communication between team members related to the implementation of risk management plan standards.
- *Resource requirements*: An evaluation of the competence of personnel in manufacturing reference materials, including the ability of subcontractors involved in the production, processing, storage, and distribution.
- *Technical and production requirements*: An assessment of the full production process of reference materials, data integrity, and traceability of values.
- *Management system requirements*: An evaluation of policy, system documents, risk assessment, and control of records.

Iso/iec 17043

This accreditation is specifically for proficiency testing providers. It has the following requirements:

- *Technical requirements*: An assessment of personnel, design, and preparation of proficiency testing schemes, data and result analysis, and records and reports.
- *Management system requirements*: An evaluation of the management system, subcontracting services, control of records, technical records, internal audits, and management reviews.

Iso/iec 17020

This accreditation is specifically for inspection bodies. It has the following requirements:

- *Structural requirements*: An assessment of organization and management and administrative needs.
- *Resource requirements*: An assessment of personal competence, work environment, equipment, and subcontracting.
- *Process requirements*: An evaluation of inspection methods and procedures, handling of inspection samples and items, inspection records, inspection certificates, and reports, complaints and appeals, and their processes.
- *Management system requirements*: An evaluation of management system documents, control of documents and records, internal audits, corrective and preventive actions, and management reviews.

Iso/iec 17065

This accreditation is specifically for product certification bodies. It has the following requirements:

- *Structural requirements*: An assessment of personnel including their training and education, communication between personnel in relation to their responsibilities within the laboratory, work environment, as well as policies and protocols used to safeguard impartiality in certification activities.
- *Resource requirements*: An evaluation of the competence of personnel in manufacturing reference materials, including the ability of subcontractors involved in the production, processing, storage, and distribution.

Iso/iec 17025

This accreditation is specifically for testing/calibration laboratories. It has the following requirements:

- *Management requirements*: An assessment of laboratory personnel competence, environmental conditions, testing, calibration, and validation methods, equipment, measurement traceability, sampling procedures, handling of test and calibration items, quality assurance, and reporting of results.
- *Technical requirements*: An evaluation of the establishment, implementation, and maintenance of a laboratory management system, document control, review of requests, tenders, and contracts, purchasing services and supplies, services to customers, control of nonconforming testing and/or calibration work, improvement, preventive and corrective actions, control of records, internal audits, and management reviews.

Good laboratory practices

Good laboratory practices (glp) is an official regulation that was created by the fda in 1978. Good laboratory practice (glp) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

The purpose of glp is to

- Ensure quality test data
- Ensure sound laboratory laboratory management
- Ensure robust conductance of laboratory testing
- Ensure accurate reporting of test findings
- Ensure safe archival of laboratory data
- The glp principles basically encompasses following points

1. Test facility organization and personnel

- Test facility management should designate personnel to assume responsibility for the quality assurance programme, and these personnel should not be involved in the conduct of the regulatory work being assured.
- Test facility management should ensure that there is a quality assurance programme, with designated personnel, and assure that the quality assurance programme is being performed in accordance with the principles of glp.

Study director's responsibilities

- Has the responsibility for the overall performance of the study and the final report.
- Approves the study plan and amendments and communicate them to the qa personnel.
- Ensures that sops, study plans and their amendments are available to study personnel.
- Ensures that the sops are followed, assess the impact of any deviations and takes appropriate corrective and preventive action.
- Ensures that raw data are documented and recorded.
- Computerized systems are validated.
- Sign and date the final report to indicate acceptance of responsibility.

- Study personnel responsibilities
- Knowledge of the glp principals
- Access to the study plan and appropriate sops
- Comply with the instructions of the sops
- Record raw data
- Study personnel are responsible for the quality of their data
- Exercise health precautions to minimize risk

2. Quality assurance (qa) programme

- Quality control is the process, procedures and authority used to accept or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products and the authority to review production records to assure that no errors have occurred, that they have been fully investigated.
- The quality and reliability of test data count on the state and condition of the test system which is used in its production.
- The test facility should have a documented quality assurance programme to guarantee that studies performed comply with these principles of good laboratory practice.
- The quality assurance programme should be performed by an individual or by individuals designated by.
- The quality assurance personnel should be responsible of maintaining copies of all approved study plans and standard operating procedures in use in the test facility and have access to an up-to-date copy of the master schedule, verifying that the study plan contains the information required for compliance with these principles of good laboratory practice, conducting inspections to determine if all studies are conducted in accordance with these principles of good laboratory practice.
- Inspections should also determine that study plans and standard operating procedures have been made available to study personnel and are being followed.
- Quality assurance thus has to find a balance in their inspectional activities, evaluating the study type and “critical phases”, in order to achieve a well supported view of the glp compliance at the test facility and within the studies conducted.
- In the final reports it should be confirmed that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies.

3. Facilities

- Glp requires that test facilities be of appropriate size, construction and location to meet the requirements of the study and minimize disturbances that would interfere with the validity of the study.
- They should be designed to provide an adequate degree of separation between the various activities of the study.
- Separation renders the assurance that different functions or activities do not interfere with each other or affect the study.
- Minimizing disturbance by separation can be achieved by:
- Physical separation: This can be achieved by walls, doors or filters, or by the use of isolators. In new buildings or those under transition or renovation, separation will be part of the design.
- Separation by organization, for example by the establishment of defined work areas within a laboratory carrying out different activities in the same area at different times, allowing for cleaning and preparation between operations or maintaining separation of staff, or by the establishment of defined work areas within a laboratory.
- Isolation of test systems and individual projects to protect from biological hazards.
- Suitable rooms for the diagnosis, treatment and control of diseases.
- Storage rooms for supplies and equipment.
- Separate areas for receipts and storage of the test and reference items.
- Separation of test items from test systems.
- Archive facilities for easy retrieval of study plans, raw data, final reports, samples of test items and specimens.
- Handling and disposal of waste in such a way not to jeopardize the integrity of the study.
- Documented inspection, cleaning, maintenance and calibration of apparatus.

4. Test systems

- Equipment, including validated computerized systems, used for the generation, storage and recovery of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.
- Equipment records should include: Name of the equipment and manufacturer, model or type for identification, serial number, and date equipment was received in the laboratory, copy of manufacturers operating instruction(s).
- Equipment used in a study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures.
- Records of these activities should be maintained.
- Calibration should be traceable to national or international standards of measurement.

- Instrumentation validation is a process necessary for any analytical laboratory.
- Data produced by "faulty" Instruments may give the appearance of valid data.
- The frequency for calibration, re-validation and testing depends on the instrument and extent of its use in the laboratory.
- Chemicals, reagents, and solutions should be labeled to indicate identity, expiry date and specific storage instructions.
- Information concerning source, preparation date and stability should be available.
- Appropriate design and adequate capacity of apparatus used for the generation of data.
- Integrity of physical/chemical test systems and biological test systems.
- Proper conditions for storage, housing, handling and care.
- Humanely destruction of inappropriate test systems.
- Records of source date of arrival and arrival conditions of test systems.
- Acclimatization of biological systems to the test environment.
- Proper identification of test systems in their housing or container or when removed.
- Cleaning and sanitization of housings or containers.

5.test and reference items

- Records including test item and reference item characterization, date of receipt, expiry date, quantities received and used in studies should be maintained.
- Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mixup are precluded.
- Storage container(s) should carry identification information, expiry date, and specific storage instructions.
- Each test and reference item should be appropriately identified (e.g., code, chemical abstracts service registry number [cas number], name, biological parameters).
- For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.
- In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.
- The stability of test and reference items under storage and test conditions should be known for all studies.
- If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined.

- For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments.

6.standard operating procedures (sop's)

- Standard operating procedures (sops) are intended to describe procedures that are routinely employed in the performance of test facility operations. Indeed they are defined as "documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines."
- A test facility should have written standard operating procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility.
- Revisions to standard operating procedures should be approved by test facility management.
- Each separate test facility unit or area should have immediately available current standard operating procedures relevant to the activities being performed therein.
- Published textbooks, analytical methods, articles and manuals may be used as supplements to these standard operating procedures.

7. Performance of the study

- Performance of the study should be monitored carefully.
- All the standards supplied by the glp should be followed from the beginning of the study to the end by the final report.
- For each study, a written plan should exist prior to the initiation of the study.
- The study plan should contain the following information: Title, nature and purpose of the study, test item identity, reference item used etc.
- Information concerning the sponsor and facility, names and address (sponsor, test facility, study director), dates approval, dates of the study plan, estimated starting and completion dates etc.
- The study plan should be approved by a dated signature of the study director and verified for glp compliance.

8. Reporting of study results

- All studies generate raw data that are the original data gathered during the conduct of a
- Raw data refers to any laboratory worksheets, records, memoranda, notes, or exact copies that are the results of original observations and activities of a study.

- The term covers all data necessary for the reconstruction of the report of the study.
- Raw data may include handwritten notes, photographs, microfiche copies, computer print-outs, magnetic media, dictated observations, and electronically recorded data from automated instruments.
- They are essential for the reconstruction of studies and contribute to the traceability of the events of a study.
- Raw data are the results of the experiment upon which the conclusions of the study will be based.

9. Storage and retention of records and materials

The following should be retained in the archives for the period specified by the appropriate authorities:

A) the study plan, raw data, samples of test and reference items, specimens, and the final report of each study;

B) records of all inspections performed by the quality assurance programme, as well as master schedules;

C) records of qualifications, training, experience and job descriptions of personnel; d) records and reports of the maintenance and calibration of apparatus;

E) validation documentation for computerised systems;

F) the historical file of all standard operating procedures;

G) environmental monitoring records.\

Good manufacturing practices

Gmp, which stands for good manufacturing practices, is a system that ensures that manufactured products—such as food, cosmetics, and pharmaceutical goods—are consistently produced and controlled according to set quality standards. Implementing gmp can help cut down on losses and waste, and avoid recalls, fines, and jail time. Overall, it protects both the company and the consumer from negative food safety events.

Gmps examine and cover every aspect of the manufacturing process to guard against any risks that can be catastrophic for products, such as cross-contamination, adulteration, and mislabeling. Some areas that can influence the safety and quality of products that gmp guideline and regulation address are the following:

- Quality management
- Sanitation and hygiene
- Building and facilities
- Equipment
- Raw materials
- Personnel
- Validation and qualification
- Complaints
- Documentation and recordkeeping
- Inspections & quality audits

It is paramount to the manufacturing industry to regulate gmp in the workplace to ensure consistent quality and safety of products. The five main components of gmp, commonly referred to as the 5p's, help organizations comply with strict standards throughout the entire production process.

1. *People* – all employees are expected to strictly adhere to manufacturing processes and regulations. A current gmp training must be undertaken by all employees to fully understand their roles and responsibilities. Assessing their performance helps boost their productivity, efficiency, and competency.
2. *Products* – all products must undergo constant testing, comparison, and quality assurance before distributing to consumers. Manufacturers should ensure that primary materials including raw products and other components have clear specifications at every phase of production. The standard method must be observed for packing, testing, and allocating sample products.
3. *Processes* – processes should be properly documented, clear, consistent, and distributed to all employees. Regular evaluation should be conducted to ensure all employees are complying with the current processes and are meeting the required standards of the organization.
4. *Procedures* – a procedure is a set of guidelines for undertaking a critical process or part of a process to achieve a consistent result. It must be laid out to all employees and followed consistently. Any deviation from the standard procedure should be reported immediately and investigated.
5. *Premises* – premises should promote cleanliness at all times to avoid cross-contamination, accidents, or even fatalities. All equipment should be placed or stored properly and calibrated regularly to ensure they are fit for the purpose of producing consistent results to prevent the risk of equipment failure.

Principles of GMP

1. Create standard operating procedures (sops)
2. Enforce / implement sops and work instructions
3. Document procedures and processes
4. Validate the effectiveness of sops
5. Design and use working systems
6. Maintain systems, facilities, and equipment
7. Develop job competence of workers
8. Prevent contamination through cleanliness
9. Prioritize quality and integrate into workflow
10. Conduct gmp audits regularly

GMP regulations

Gmp regulations are mandated by manufacturers' respective national governments to regulate the production, verification, and validation of manufactured products and ensure that they are effective and safe for market distribution.

For example, in the united states, gmp is enforced by the us fda through current good manufacturing practices (cgmp) which cover a broader range of industries such as cosmetics, food, medical devices, and prescription drugs. The fda conducts facility inspections to assess if a manufacturing company complies with cgmp regulations. If any serious violations are found during the inspection, fda recalls all products, which is problematic for manufacturers in terms of both profit and business operations.

The quality of manufactured products is highly regulated as it can pose negative health risks to consumers and even the environment. Poor hygiene, temperature-control, cross-contamination, and adulteration in any step of the manufacturing process are some examples of how a manufactured product that doesn't follow gmp regulations can bring fatal consequences to consumers. See gmp regulation and preamble sources by country here.

UNIT -2

International Institutions

➢ Wipo

The world intellectual property organisation or wipo is a global body for the promotion and protection of intellectual property rights (ipr).

- It acts as a global forum for ip services.
- Wipo is a self-funded agency of the united nations.
- With **192 members**, wipo's motto is to encourage creative activity, to promote the protection of intellectual property throughout the world.
- It is at present headed by francis gurry, who is its director-general. Wipo is headquartered in geneva, switzerland.
- Wipo has its origins in the united international bureaux for the protection of intellectual property (**birpi**), which was established in 1893.

Wipo's mandate

'wipo is dedicated to developing a balanced and accessible international intellectual property (ip) system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest.'

Functions of wipo

The world intellectual property organisation (wipo) was established with the intent to perform the following functions:

- To assist the development of campaigns that improve ip protection all over the globe and keep the national legislations in harmony.
- Signing international agreements related to intellectual property rights (ipr) protection.
- To implement administrative functions discussed by the berne and paris unions.
- To render legal and technical assistance in the field of ip.
- To conduct research and publish its results as well as to collect and circulate information.

- To ensure the work of services that facilitate the international intellectual property protection.
- To implement other appropriate and necessary actions.

Wipo treaties

Name of the treaty	**Description**
Wipo performance and phonograms treaty (wppt)	Wppt deals with the rights of two types of beneficiaries, especially in the digital environment: For example: • Singers, actors, musicians, etc. (performers) • Producers of phonograms
Budapest treaty	International recognition of the deposit of microorganisms for the purposes of patent procedure was the purpose of this treaty.
Madrid protocol for the international registration of marks	The protocol ensures the protection of a mark in many countries by securing an international registration that has an effect in all of the designated contracting parties.
Marrakesh treaty to facilitate access to published works by visually impaired persons and persons with print disabilities	Marrakesh treaty allowed copyright exceptions that facilitated the creation of accessible versions of books. It also provided copyrighted works for the visually impaired.
Wipo copyright treaty	It dealt with the protection of works and the rights of their authors in the digital environment.

Wipo and india

India joined the wipo in 1975.

India is a part of the following wipo treaties:

- Ipo convention (1975)
- Paris convention (1998)
- Berne convention (1928)
- Patent cooperation treaty (1998)
- Phonograms convention (1975)
- Nairobi treaty (1983)
- Nice agreement (2019)
- Locarno agreement (2019)
- Vienna agreement (2019)

India acceded to all of the above treaties. India was the first country to ratify the marrakesh treaty.

India has jumped places in the global innovation index (gii) in recent years. In the 2019 gii, india is ranked 52nd, which is a big leap from previous years.

- Since 2011, india is the top-ranked innovative country in the southern and central asia region.
- India has been outperforming on innovation relative to its gdp per capita for eight years at a stretch.
- On innovation quality, india ranks second among middle-income economies globally.
- The confederation of indian industry (cii) is a gii knowledge partner since 2009.
- In india, the ministry of commerce and industry deals with wipo and related issues.

Wipo publications

The global innovation index (gii) is a global ranking for countries for success in and capacity for innovation.

- It is published by the wipo in association with cornell university and graduate business school insead.
- The index ranks countries based on 80 indicators, ranging from intellectual property filing rates to research and development, online creativity, mobile application creation, computer software spending, education spending, scientific & technical publications and ease of starting a business.

➢ WTO

Wto – world trade organisation, was established in 1995 as the heir organisation to the gatt (general agreement on trade and tariff). Gatt was founded in 1948 with 23 nations as the global (international) trade organisation to serve all multilateral trade agreements by giving fair chances to all nations in the international exchange for trading prospects. Wto is required to build a rule-based trading government in which countries cannot place unreasonable constraints on trade.

In addition, its mission is to increase stock and trade of services, to assure maximum utilisation of world resources and to preserve the environment. The wto deals include trade in commodities as well as services to promote international trade (bilateral and multilateral) through the elimination of the tax as well as non-tariff obstacles and implementing greater marketplace access to all member nations.

As an influential member of wto, india is at the lead of building fair global laws, statutes and shields and supporting the concerns of the developing system. India has fulfilled its promises towards the liberalisation of trade, made in the wto, by eliminating quantitative limitations on imports and decreasing tariff charges.

Objectives of wto

- To set and execute rules for international trade
- To present a panel for negotiating and controlling additional trade liberalization
- To solve trade conflicts
- To improve the clarity of decision-making methods
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➢ Trips

The trade-related aspects of intellectual property rights (trips) agreement is in the news now because of the recent us decision to support the temporary waiver of patent rules for the coronavirus vaccines. This is an important topic from multiple perspectives for the upsc exam including economy, international relations, current affairs, etc.

Trips agreement

Trade related aspects of intellectual property right (trips) is an agreement on international ip rights.

- Trips came into force in 1995, as part of the agreement that established the world trade organisation (wto).

- Trips establishes minimum standards for the availability, scope, and use of seven forms of intellectual property namely, trademarks, copyrights, geographical indications, patents, industrial designs, layout designs for integrated circuits, and undisclosed information or trade secrets.
- It applies basic international trade principles regarding intellectual property to member states.
- It is applicable to all wto members.
- Trips agreement lays down the permissible exceptions and limitations for balancing the interests of intellectual property with the interests of public health and economic development.
- Trips is the most comprehensive international agreement on ip and it has a major role in enabling trade in creativity and knowledge, in resolving trade disputes over intellectual property, and in assuring wto members the latitude to achieve their domestic policy objectives.
- It frames the ip system in terms of innovation, technology transfer and public welfare.
- The trips council is responsible for administering and monitoring the operation of the trips agreement.
- Trips was negotiated during the uruguay round of the general agreement on tariffs and trade (gatt) in 1986–1994.

➢ Paris convention

The paris convention covers all forms of industrial property, such as patents, trademarks, industrial designs, utility models, geographical indications, service marks, trade names, and the prevention of unfair competition.

The paris convention was created with two goals, which are-

- First, to prevent the unforeseen loss of patent protection eligibility by publishing 81 patent applications and taking part in international exhibitions before submitting national patent applications; and
- Second, to some extent, harmonise the various patent laws of the various countries.
- The substantive provisions of the paris convention can be divided into three main categories-

1. **National treatment**– as per the terms and conditions of the convention, every secretary state must ensure that the citizens of their nation and the citizens of other contracting states have an equivalent degree of protection regarding industrial property. Citizens of non-contracting states shall be entitled to national treatment under the convention in the same manner as in their own

state if they reside in the contracting state or have a lawful and functioning industrial or commercial presence there.

2. **Priority rights**– it covers within its ambit industrial designs, trademarks, and utility models. This right gives the holder the ability to file an application for protection in any other contracting state within a certain amount of time, that is, 6 months for industrial designs and trademarks and 12 months for patents and utility models, based on a standard initial application that was filed in one of the contracting states. It would be assumed that these additional applications were filed on the same day as the first application. To state it otherwise, it means that they will supersede any application filed by third parties for the same invention, utility model, trademark or industrial design during the previously indicated term.
3. The subsequent applications would not be influenced by any subsequent event, including the publication of an invention or the sale of items bearing an industrial design or mark, because they have their foundation in the original application.

Common rules – they are as under:

- **Patents**– patents issued for the same invention in different contracting states are independent of one another. A patent cannot be refused, cancelled, or terminated in any contracting state on the grounds that it has already been so in another contracting state, and the granting of a patent in one contracting state does not obligate other contracting states to do the same. The refusal to award a patent or the invalidation of a patent on the grounds that the sale of the product or of a product made using the patented technique is subject to domestic legal restrictions or limitations is not permitted.
- **Marks**– the filing and registration requirements for marks are governed by local law in each contracting state and are not governed by the paris convention. As a result, neither a registration nor a request for registration of a mark that is put forward by a citizen of any contracting state may be denied or invalidated on the grounds that the application, registration, or renewal was unaffected in the country of origin.
- **Registration**– a trademark's registration in one contracting state is unrelated to any potential registrations in other nations, including the place of origin.
- **Industrial designs**– each contracting state is required to preserve industrial designs, and protection cannot be revoked because products containing the design were not produced there.
- **Trade names**– trade names must be protected in every contracting state without being required to file or register the names.

- **An indication of source**– each contracting state is required to take action to prevent the direct or indirect use of misrepresentations regarding the origin of commodities or the identity of their producer, maker, or trader.
- **Unfair competition**– each contracting state shall offer adequate safeguards against unfair competition.

Budapest treaty

The budapest treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure, 1977 is a landmark for its central provision that any contracting state that permits or mandates the deposit of microorganisms for the purposes of patent procedure shall recognise, for such purposes, the deposit of a microorganism with any "international depositary authority," Regardless of whether that authority is on or outside the territory of the said state.

In actual usage, the phrase "microorganism" Is defined broadly to include any biological material that must be deposited for disclosure reasons, particularly in the case of inventions in the food and pharmaceutical industries.

The innovation must be disclosed in order for a patent to be granted. A written description is typically used to reveal an invention. When an invention involves the use of a microbe that is not generally available to the public, disclosure cannot be made in writing and must instead be accomplished by depositing a sample of the microorganism with a specialised institution.

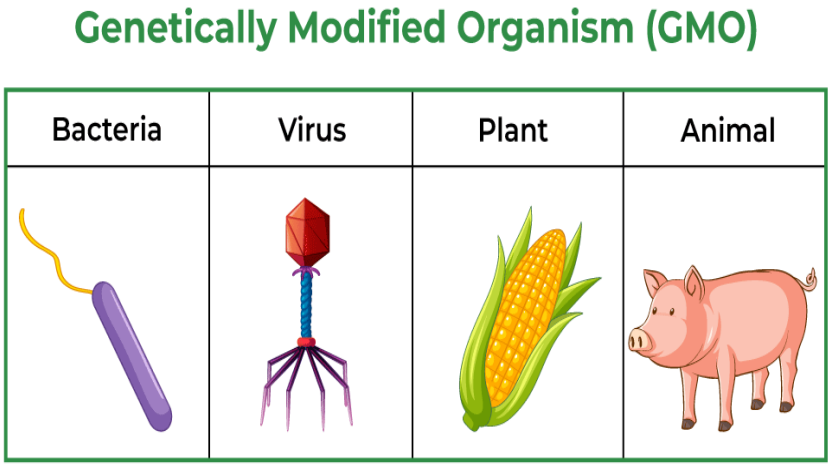
UNIT - 3

Genetically modified organisms

Genetically modified organisms (gmos) are used in laboratories for research to know the organism and its function in a better way. Biotechnology is the field of study that involves the application of biological systems, organisms, or cells to make products that benefit human beings. Genetically modified organisms have become a focal point in discussion in various areas such as medicine, agriculture, and the environment. Gmos have also been a point of discussion from the viewpoint of ***ethical issues***. I

Genetically modified organisms (gmos)

Gmos are organisms whose genetic material has been altered, unlike natural mating or recombination. The objective of genetic modification is to introduce desirable traits/features into the organisms so that their benefit can be used for various purposes. For example, genetically modified crops can be designed in such a way as to be resistant to pests and herbicides, which will lead to increased yields and reduced use of harmful chemicals and pesticides in agricultural processes.



The use of genetically modified organisms (gmos) has grown very quickly in the last few years and it led to the development of new products and solutions for human benefit. Genetically modified organisms applications can be seen in various fields like agriculture, medicine, and industry etc,. In the agricultural field, gmos are used to improve the yields of crops by making them resistant to pests and diseases and enabling tolerance to environmental stresses such as drought and salinity. Genetically modified organisms application in medicine is to produce therapeutic proteins and vaccines. Gmos are also used for the production of biofuels, biodegradable plastics, e.t.c. In industrial use cases.

Ethical issues associated with genetically modified organisms (gmos)

- ***Ethical issues regarding safety:*** The safety of gmos has been under much debate and concern. It is a common fear that genetic modification may result in unintended consequences, such as the creation of new allergens or toxins, the spread of modified genes to wild relatives, or the development of antibiotic-resistant bacteria. These safety concerns led to calls for rigorous testing and regulation of gmos.
- ***Ethical issues regarding health:*** There exist concerns about potential health risks associated with it. Some studies suggested that gmos may cause allergies or other health effects, although there's a lack of concrete evidence to support these. Additionally, concerns that gmos may contribute to the development of new diseases or the spread of any existing diseases.
- ***Ethical issues regarding the environment:*** The release of gmos into the environment has the potential to cause ecological damage. For example, a common fear is that genetically modified crops may cross-breed with any wild relatives, resulting in the spread of modified genes and the creation of invasive species. Additionally, concern that gmos negatively impact ecosystems by reducing biodiversity and disrupting food webs.
- ***Patents and access to seeds:*** The issue of patents and access to seeds is another ethical issue associated with gmos. Many corporations hold patents on genetically modified seeds, which can make it difficult for farmers to access the seeds they need to grow crops. This has led to concerns about corporate control of the food supply and the impact this may have on farmers and consumers.
- ***Ownership of life:*** The idea of manipulating the genetic makeup of living organisms raises ethical questions about the ownership of life. Some argue that it is unethical to manipulate the genetic material of living organisms for commercial purposes, while others believe that genetic modification is a necessary tool for improving the quality of life for people around the world.
- ***It's public perception:*** Yes, the public perception of gmos is also a major ethical issue. Despite the fact that there are many potential benefits of gmos, many of us are wary of them due to concerns about their safety and potential impact on the environment and our own health. So, there's an absolute need for public education and awareness about the benefits and risks of gmos to help mitigate these concerns.

Applications and implementations of gmos

The uses of genetically modified organisms is observed in various fields. Some of them are discussed below:

Genetically modified organisms in *agriculture*

A primary application of gmos is in the agricultural field. Genetically modified crops are developed to improve yields, reduce the need for pesticides and herbicides, and provide resistance to disease and pests. For example, genetically modified crops such as bt cotton and bt brinjal contain genes from the bacterium bacillus thuringiensis which produce insecticidal proteins, which provide resistance to pests and reduce the need for chemical pesticides.

Genetically modified organisms in *medicine*

Biotechnology also has a significant impact on medicine. Genetically modified organisms are used to produce new drugs and therapies, such as monoclonal antibodies, vaccines, and enzymes. For example, the production of insulin which is used to treat diabetes has been revolutionized by the use of genetically modified bacteria.

Genetically modified organisms in industry

Gmos have also been used in various industrial applications. For example, genetically modified bacteria are being used to produce biofuels, such as ethanol and biodiesel, and to break down toxic waste. In addition, genetically modified yeasts are being used to produce ingredients for food and beverages, such as flavors and fragrances.

Environmental cleanup

Gmos have also been used in environmental cleanup efforts. For example, genetically modified bacteria have been used to break down toxic pollutants, such as oil spills, and to remove heavy metals from contaminated soil.

Conclusion: Genetically modified organisms-ethical issues

In conclusion, genetically modified organisms (gmos) have become a main point of discussions surrounding their application across various sectors like medicine, agriculture, and industry. While they offer promising solutions, ethical concerns related to genetically modified organisms regarding safety, health, environmental impact, and accessibility persist. Despite these challenges, gmos have shown significant potential in increasing crop yields, producing therapeutic drugs, and addressing environmental concerns. Efforts towards public education and awareness are crucial to take informed decision-making and responsible implementation of genetically modified organisms technologies.

Intellectual property rights

The definition of intellectual property rights is any and all rights associated with intangible assets owned by a person or company and protected against use without consent. Intangible assets refer to non-physical property, including right of ownership in intellectual property . Examples of intellectual property rights include:

- Patents
- Domain names
- Industrial design
- Confidential information
- Inventions
- Moral rights
- Database rights
- Works of authorship
- Service marks
- Logos
- Trademarks
- Design rights
- Business or trade names
- Commercial secrets
- Computer software

Types of intellectual property

There are four main types of intellectual property rights, including patents, trademarks, copyrights, and trade secrets. Owners of intellectual property frequently use more than one of these types of intellectual property law to protect the same intangible assets. For instance, trademark law protects a product's name, whereas copyright law covers its tagline.

1. Patents

The u.s. Patent and trademark office grants property rights to original inventions, from processes to machines. Patent law protects inventions from use by others and gives exclusive rights to one or more inventors. Technology companies commonly use patents, as seen in the patent for the first computer to protect their investment in creating new and innovative products. The three types of patents consist of:

- *Design patents:* Protection for the aesthetics of a device or invention. Ornamental design patents include a product's shape (coca-cola bottle), emojis, fonts, or any other distinct visual traits.

- *Plant patents:* Safeguards for new varieties of plants. An example of a plant patent is pest-free versions of fruit trees. But inventors may also want a design patient if the tree has unique visual properties.
- *Utility patents:* Protection for a product that serves a practical purpose and is useful. Ip examples include vehicle safety systems, software, and pharmaceuticals. This was the first, and is still the largest, area of patent law.

2. Trademarks

Trademarks protect logos, sounds, words, colors, or symbols used by a company to distinguish its service or product. Trademark examples include the twitter logo, mcdonald's golden arches, and the font used by dunkin.

Although patents protect one product, trademarks may cover a group of products. The lanham act, also called the trademark act of 1946, governs trademarks, infringement, and service marks.

3. Copyrights

Copyright law protects the rights of the original creator of original works of intellectual property. Unlike patents, copyrights must be tangible. For instance, you can't copyright an idea. But you can write down an original speech, poem, or song and get a copyright.

Once someone creates an original work of authorship (owa), the author automatically owns the copyright. But, registering with the u.s. Copyright office gives owners a head-start in the legal system.

4. Trade secrets

Trade secrets are a company's intellectual property that isn't public, has economic value, and carries information. They may be a formula, recipe, or process used to gain a competitive advantage.

To qualify as a trade secret, companies must work to protect proprietary information actively. Once the information is public knowledge, then it's no longer protected under trade secrets laws. According to 18 usc § 1839(3), assets may be tangible or intangible, and a trade secret can involve information that's:

- Business
- Financial
- Technical
- Economic
- Scientific
- Engineering

Two well-known examples include the recipe for coca-cola and google's search algorithm. Although a patent is public, trade secrets remain unavailable to anyone but the owner.

Patent

Before getting into detail about what a patent is, let's discuss something else first. You have a talent for construction and a desire to amass wealth. Unfortunately, that idea was never realized since someone else stole your idea because you were unaware of a (not so) minor thing called patents. By registering your idea for a patent, all of this can be prevented.

A patent is a legal document that the government issues to the creator, giving him the exclusive right to sell, manufacture, use, and import the invention for a predetermined amount of time following the publication of the idea. By limiting who can sell their products on their behalf, patents are required by law to safeguard innovators. The sources of the phrase "patent" Are old french, old latin, and old english. From the latin "*patentem"* And french "*patente*", which both indicate the open letter, it first appeared in the late 13th century. In the 1580s, the phrase took on its current meaning when it was explained as a government-issued permit to create and sell a specific good.

A patent is used in business to develop, promote, and sell a product. For many of the products that people purchase, patents are employed. Once a patent application has been accepted by the government, it generally lasts for 20 years from the application date. An official government letter patent is the document that gives a person or business the sole right to sell a product. The patent applicant or seller may start collecting royalties for their goods once the patent has been processed and authorized. A royalty is a payment made to the creator of a product in exchange for the right to use it; it serves as reimbursement for their labor. This might take the form of a television commercial producer paying a songwriter royalties for the usage of their music in a commercial. At least until the product is released to the market, patents and royalties are typically maintained confidentially by firms through solid agreements and trade secrets. Regardless of whether a patent application is filed with a provisional or complete specification, all indian patents have a 20-year term beginning on the date of filing. The 20-year period, however, starts on the date of the international filing for applications submitted under the patent cooperation treaty (pct).

Patent law amendment act 2005

Salient features of the patents (amendment) act 2005 related to product patents:

1. Extension of product patent protection to products in sectors of drugs, foods and chemical.
2. Term for protection of product patent shall be for 20 years.

3. Introduction of a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity; provided such importing country has either granted a compulsory license for import or by notification or otherwise allowed importation of the patented pharmaceutical products from india (in accordance with the doha declaration on trips and public health)
4. Section 3 (d) regarding patentability.

Effects of patent amendment act 2005

1. Due to the new patent regime, increased prices of products was considered to be a major hindrance during the time. However, the government has taken proactive measures to ensure low prices for essential drugs, and has used compulsory licensing as a tool to keep exorbitant prices under check.
2. The amendment intended to make indian drug and pharmaceutical industries competitive at par with multinational companies.
3. Despite initial reservations, indian pharmaceutical companies manufacturing generic drugs have flourished in the last decade.
4. Also, mncs have opened research and development centres in india.

Types of patents

To protect various types of inventions, various forms of patents are available. Competent innovators can use the various patent application types to obtain the legal protection they require for their discoveries:

Utility patent

When most people hear the word “patent,” They generally think of inventions covered by utility patents. A utility patent is a technical document that describes in great detail how a new device, method, or system operates and provides a strong form of protection. A wide variety of inventions, including the broom, computers, business procedures, and medications, have been protected under this patent. The utility patent duration is 20 years.

Design patent

This patent protects adornment on a practical object. A design patent, for instance, can safeguard the appearance of a shoe or a bottle. The majority of the actual paper is made up of images or sketches that depict the useful item’s design. Because a design patent uses so few words, they are notoriously challenging to search for. Software businesses have recently exploited design patents to safeguard user interface

components, even the design of touchscreen devices. The design of the invention must be both practical and unique. The original coca-cola bottle design is an illustration of this kind of patent. The design patent duration is 15 years.

Plant patent

A plant patent covers novel varieties of plants developed through cuttings or other non-sexual methods, as the name implies. Genetically modified species are typically excluded from the scope of plant patents, which instead emphasize traditional gardening. The plant patent duration is 20 years.

Types of patent applications

There are four types of patent applications:

Provisional patent application

When you are not quite finished with your idea and want to draw time to continue working on the research and creation of your innovation while at the same time not wanting to lose out on the priority date, you file a provisional application. It's possible for a tentative specification to have claims or not. You have 12 months from the date of filing a provisional application to submit a full patent application. Your application will be canceled if you don't submit a full patent application within 12 months following the filing of your provisional patent application.

Divisional patent application

If a claimant's application includes claims to more than one invention, the claimant may split the application and submit two or more applications, one for each invention, on his own or in response to an official objection. A divisional application is a kind of application that is split from its parent application. All divisional applications shall have the same stated priority date as the parent application. A divisional application's patent period is 20 years from the time the main application was filed.

Additional patent application

An application for a patent of addition may be made by the applicant when he develops an enhancement or modification of the invention specified or revealed in the main application for which he has already made an application or secured a patent. Only after the main or parent patent has been obtained may an additional patent be issued. Throughout the duration of the primary patent, there is no need to pay a separate renewal

fee for the patent of addition. A patent of addition must be issued for the same duration as the patent for the primary invention and terminates with it. The date of filing is the day that the patent application for the addition was submitted.

Complete patent application

A complete application is one that is submitted along with a complete specification that fully and specifically describes the invention, including the best way to implement it. It may be submitted immediately or within a year of the provisional patent application's submission.

Criteria for patentability

Only if an innovation complies with the criteria for patentability will it be eligible for a patent grant in india. The innovation must meet all of the conditions that evaluate its suitability for a patent grant from various angles to be considered patentable. Compared to other standards, some of them are easier to meet, but all of them are equally crucial for determining patentability. The following are the three requisites for patentability criteria:

Novelty

Only if a product or method is both innovative and inventive, will it be regarded as an invention under the patents act. Simply said, novelty refers to anything being new compared to what it was on the priority date of the patent application. If an innovation departs from the "prior art," Which is what already exists, it will be seen as unique. Previous art references are never pooled for novelty analysis; rather, novelty is always evaluated in light of a particular prior art reference at a time. However, a prior art citation may be interpreted to include general knowledge of the art that isn't stated explicitly in the reference. Novelty is included in many sections relating to inspection, anticipation, objection, and revocation but is not defined by the patents act.

Inventive step

Of all the criteria for patentability, the inventive step criterion is the most ambiguous and difficult to define. The indian patents act offers non-obviousness and technical advancement or economic relevance as two criteria for evaluating inventive steps. The patents act defines inventive steps in section 2(ja). The inventor must make a creative contribution to the invention. It needs to be something that a skilled craftsperson wouldn't anticipate. Let's say an innovator creates a device to address a technological issue. A different expert in the same sector offers the same solution by drawing on his knowledge or absorbing instruction.

The inventor's technological solution won't be regarded as original in that situation because it was just a suggestion or motive. The supreme court defined the term "inventive step" In the biswanath prasad radhey shyam case in 1978, and it is being used for inventive step analysis today.

Industrial application

According to section 2(ac) of the patents act, "the creation is a patent of being used or created in a sector." It implies that a product must be useful to be patentable because the invention cannot exist in a vacuum and must apply to all fields. A product will be deemed to be industrially applicable if it can be produced consistently and has at least one application in a given industry. For a procedure to meet this condition, the industry must be able to employ it. Users that are uncertain, hazy, future, or non-specific are not regarded as legitimate users. The same is true when a product or procedure is used in a minimal or untrustworthy way.

The delhi high court noted that an invention must be economically feasible in a case involving cipla and roche after reviewing various indian and international cases about the utility or industrial application criteria. Commercial use is required, although commercial development need not be demonstrated. Fundamentally, the invention must serve the function stated in a patent specification and have a practical application. Nothing more will be necessary to demonstrate an invention's utility for patentability.

UNIT -4

Basic research

Basic research is a type of research used in the scientific field to understand and extend our knowledge about a specific phenomenon or field. It is also accepted as pure investigation or fundamental research.

This type of research contributes to the intellectual body of knowledge. Basic research is concerned with the generalization of a theory in a branch of knowledge; its purpose is usually to generate data that confirm or refute the initial thesis of the study.

It can also be called foundational research; many things get built on this foundation, and more practical applications are made.

Basic research examples

There can be many examples of basic research; here are some of them:

- A study of how stress affects labor productivity.
- Studying the best factors of pricing strategies.
- Understand the client's level of satisfaction before certain interactions with the company providing solutions.
- The understanding of the leadership style of a particular company.

Advantages & disadvantages

Basic research is critical for expanding the pool of knowledge in any discipline. The introductory course usually does not have a strict period, and the researcher's concern commonly guides them. The conclusion of the fundamental course is generally applicable in a wide range of cases and plots.

At the same time, the basic study has disadvantages as well. The findings of this type of study have limited or no constructive conclusions. In another sense, fundamental studies do not resolve complex and definite business problems, but it does help you understand them better.

Taking actions and decisions based on the results of this type of research will increase the impact these insights may have on the problem studied if that is the purpose.

Applied research

Applied research is a non-systematic way of finding solutions to specific research problems or issues. These problems or issues can be on an individual, group, or societal level. It is called "non-systematic" Because it goes straight to finding solutions.

It is often called a "scientific process" Because it uses the available scientific tools and puts them to use to find answers.

Like in regular research, the researcher identifies the problem, makes a hypothesis, and then experiments to test it. It goes deeper into the findings of true or basic research.

Types of applied research

This research has three types:

- Evaluation research,
- Research and development
- Action research.

The short versions of each type are explained below:

➢ Evaluation research

Evaluation research is one type of applied research. It looks at the information on a research subject. This kind of research leads to objective research or helps people make better decisions sooner. Most of the time, evaluation research is used in business settings.

The organization uses this research to figure out how the overhead costs can be cut down or cut down a lot.

➢ Research and development

Research and development is the second type of applied research. Its main goal is to create or design new products, goods, or services that meet the needs of certain markets in society. It finds out what the needs of the market are. It focuses on finding new ways to improve products that already meet an organization's needs**.**

➢ Action research

Action research is the third type of applied research. Action research is a way to learn about things that happen in everyday life and nature. Its goal is to find real-world solutions to business problems by pointing the business in the right direction.

- Examples of applied research

Applied study is used in many areas of study and research, from the sciences to the social sciences. We also talk about how it's used in those fields and give some examples:

1. Applied study in business

Applied study in business sectors is fully dependent on their products and services. It helps organizations understand market needs and trends, and then shape their products to fit customers.

Businesses benefit from this research because it allows them to detect gaps in their findings and obtain primary information on target market preferences.

Example:

- It can improve hiring.
- It improves work and policy.
- It identifies workplace skill gaps.

2. Applied study in education

The applied study is used in the education field to test different ways of teaching and to find better ways of teaching and learning. Before implementing new education policies, they are tested to see how well they work, how they affect teaching, and how the classroom works.

Applied education research uses quantitative and qualitative methods to collect data from first-hand sources. This information is then looked at and interpreted differently to generate valuable results or conclusions.

Most applied research in this field is done to develop and test different ways of doing things by trying them out in different situations. It is based on accurate observations and descriptions of the real world.

Example:

- Applied study to understand the reach of online learning initiatives.
- Applied study to promote teacher-student classroom engagement.
- Applied study on the new math program.

3. Applied study in science

As already said, applied study is often called a scientific process because it uses the available scientific tools to find answers. It can be used in physics, microbiology, thermodynamics, and other fields.

Example:

- The applied study is put into practice to cure a disease.
- The applied study is put into practice to improve agricultural practices.
- The applied study is applied to testing new laboratory equipment.

4. Applied study in psychology

Researchers use this research in psychology to figure out how people act at work, how hr works, and how the organization is growing and changing so they can come up with solutions.

It is used a lot in areas where researchers try to figure out how people think and then come up with solutions that fit their behavior best.

Example:

- Applied study to figure out new ways to deal with depression.
- Applied study to improve students' grades by emphasizing practical education.
- Applied study to create a plan to keep employees coming to work regularly.

5. Applied study in health

This research is used to examine new drugs in the medical industry. It combines scientific knowledge and procedures with health experiences to produce evidence-based results.

Example:

- Applied study in heart surgery.
- Applied study to determine a drug's efficacy.
- Applied study on a medicine's adverse effects.

Conclusion

Applied research is an important way to research because it helps organizations find real-world solutions to specific problems while also increasing their output and productivity. In contrast to basic research, which focuses on making theories that explain things, applied research focuses on describing evidence to find solutions**.**

In the applied study, the researcher uses qualitative and quantitative methods to collect data, such as questionnaires, interviews, and observation methods. Conducting interviews is one of the examples of qualitative data in education. It helps the researcher collect real-world evidence, which is then tested depending on the type of applied research and the main focus.

At question pro, we give researchers access to a library of long-term research insights and tools for collecting data, like our survey software. Go to insighthub if you want to see a demo or learn more about it.

Research process

Steps

The research process consists of a series of systematic procedures that a researcher must go through in order to generate knowledge that will be considered valuable by the project and focus on the relevant topic.

To conduct effective research, you must understand the research process steps and follow them. Here are a few steps in the research process to make it easier for you:

Step 1: Identify the problem

Finding an issue or formulating a research question is the first step. A well-defined research problem will guide the researcher through all stages of the research process, from setting objectives to choosing a technique. There are a number of approaches to get insight into a topic and gain a better understanding of it. Such as:

- A preliminary survey
- Case studies
- Interviews with a small group of people
- Observational survey

Step 2: Evaluate the literature

A thorough examination of the relevant studies is essential to the research process. It enables the researcher to identify the precise aspects of the problem. Once a problem has been found, the investigator or researcher needs to find out more about it.

This stage gives problem-zone background. It teaches the investigator about previous research, how they were conducted, and its conclusions. The researcher can build consistency between his work and others through a literature review. Such a review exposes the researcher to a more significant body of knowledge and helps him follow the research process efficiently.

Step 3: Create hypotheses

Formulating an original hypothesis is the next logical step after narrowing down the research topic and defining it. A belief solves logical relationships between variables. In order to establish a hypothesis, a researcher must have a certain amount of expertise in the field.

It is important for researchers to keep in mind while formulating a hypothesis that it must be based on the research topic. Researchers are able to concentrate their efforts and stay committed to their objectives when they develop theories to guide their work.

Step 4: The research design

Research design is the plan for achieving objectives and answering research questions. It outlines how to get the relevant information. Its goal is to design research to test hypotheses, address the research questions, and provide decision-making insights.

The research design aims to minimize the time, money, and effort required to acquire meaningful evidence. This plan fits into four categories:

- Exploration and surveys
- Experiment
- Data analysis

- Observation

Step 5: Describe population

Research projects usually look at a specific group of people, facilities, or how technology is used in the business. In research, the term population refers to this study group. The research topic and purpose help determine the study group.

Suppose a researcher wishes to investigate a certain group of people in the community. In that case, the research could target a specific age group, males or females, a geographic location, or an ethnic group. A final step in a study's design is to specify its sample or population so that the results may be generalized.

Step 6: Data collection

Data collection is important in obtaining the knowledge or information required to answer the research issue. Every research collected data, either from the literature or the people being studied. Data must be collected from the two categories of researchers. These sources may provide primary data.

- Experiment
- Questionnaire
- Observation
- Interview

Secondary data categories are:

- Literature survey
- Official, unofficial reports
- An approach based on library resources

Step 7: Data analysis

During research design, the researcher plans data analysis. After collecting data, the researcher analyzes it. The data is examined based on the approach in this step. The research findings are reviewed and reported.

Data analysis involves a number of closely related stages, such as setting up categories, applying these categories to raw data through coding and tabulation, and then drawing statistical conclusions. The researcher can examine the acquired data using a variety of statistical methods.

Step 8: The report-writing

After completing these steps, the researcher must prepare a report detailing his findings. The report must be carefully composed with the following in mind:

- **The layout:** On the first page, the title, date, acknowledgments, and preface should be on the report. A table of contents should be followed by a list of tables, graphs, and charts if any.
- **Introduction:** It should state the research's purpose and methods. This section should include the study's scope and limits.
- **Summary of findings:** A non-technical summary of findings and recommendations will follow the introduction. The findings should be summarized if they're lengthy.
- **Principal report:** The main body of the report should make sense and be broken up into sections that are easy to understand.
- **Conclusion:** The researcher should restate his findings at the end of the main text. It's the final result.

Conclusion

The research process involves several steps that make it easy to complete the research successfully. The steps in the research process described above depend on each other, and the order must be kept. So, if we want to do a research project, we should follow the research process steps.