

# **IDHAYA COLLEGE FOR WOMEN, KUMBAKONAM**



## **DEPARTMENT OF MICROBIOLOGY**

**CLASS : III B.Sc MICROBIOLOGY**

**SUBJECT NAME : MICROBIAL BIOTECHNOLOGY  
AND BIOETHICS**

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## UNIT-V

### INTELLECTUAL PROPERTY

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Intellectual property (IP) is a category of property that includes intangible creations of the human intellect. There are many types of intellectual property, and some countries recognize more than others. The most well-known types are copyrights, patents, trademarks, and trade secrets

The main purpose of intellectual property law is to encourage the creation of a wide variety of intellectual goods. To achieve this, the law gives people and businesses property rights to the information and intellectual goods they create, usually for a limited period of time. This gives economic incentive for their creation, because it allows people to profit from the information and intellectual goods they create. These economic incentives are expected to stimulate innovation and contribute to the technological progress of countries, which depends on the extent of protection granted to innovators.

### INTELLECTUAL PROPERTY RIGHTS

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Intellectual property rights include patents, copyright, industrial design rights, trademarks, plant variety rights, trade dress, geographical indications, and in some jurisdictions trade secrets.

#### **Patents**

A patent is a form of right granted by the government to an inventor or their successor-in-title, giving the owner the right to exclude others from making, using, selling, offering to sell, and importing an invention for a limited period of time, in exchange for the public disclosure of the invention. An invention is a solution to a specific technological problem, which may be a product or a process and generally has to fulfill three main requirements: it has to be new, not obvious and there needs to be an industrial applicability. To enrich the body of knowledge and stimulate innovation, it is an obligation for patent owners to disclose valuable information about their inventions to the public.

#### **Copyright**

A copyright gives the creator of an original work exclusive rights to it, usually for a limited time. Copyright may apply to a wide range of creative, intellectual, or artistic forms, or "works". Copyright does not cover ideas and information themselves, only the form or manner in which they are expressed.

#### **Industrial design rights**

An industrial design right (sometimes called "design right" or *design patent*) protects the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or composition of pattern or color, or combination of pattern and color in three-dimensional form containing aesthetic value. An industrial design can be a two- or three-dimensional pattern used to produce a product, industrial commodity or handicraft. Generally speaking, it is what makes a product look appealing, and as such, it increases the commercial value of goods.

## **Plant varieties**

Plant breeders' rights or plant variety rights are the rights to commercially use a new variety of a plant. The variety must amongst others be novel and distinct and for registration the evaluation of propagating material of the variety is considered.

## **Trademarks**

A trademark is a recognizable sign, design or expression which distinguishes products or services of a particular trader from similar products or services of other traders.

## **Trade dress**

Trade dress is a legal term of art that generally refers to characteristics of the visual and aesthetic appearance of a product or its packaging (or even the design of a building) that signify the source of the product to consumers.

## **Trade secrets**

trade secret is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors and customers. There is no formal government protection granted; each business must take measures to guard its own trade secrets (e.g., Formula of its soft drinks is a trade secret for Coca-Cola.)

## **PRINCIPLES OF BIOETHICS**

Bioethicists often refer to the four basic principles of health care ethics when evaluating the merits and difficulties of medical procedures. Ideally, for a medical practice to be considered "ethical", it must respect all four of these principles: autonomy, justice, beneficence, and non-maleficence. The use of reproductive technology raises questions in each of these areas.

- **Autonomy**

Requires that the patient have autonomy of thought, intention, and action when making decisions regarding health care procedures. Therefore, the decision-making process must be free of coercion or coaxing. In order for a patient to make a fully informed decision, she/he must understand all risks and benefits of the procedure and the likelihood of success. Because ARTs are highly technical and may involve high emotions, it is difficult to expect patients to be operating under fully-informed consent.

- **Justice**

The idea that the burdens and benefits of new or experimental treatments must be distributed equally among all groups in society. Requires that procedures uphold the spirit of existing laws and are fair to all players involved. The health care provider must consider four main areas when evaluating justice: fair distribution of scarce resources, competing needs, rights and obligations, and potential conflicts with established legislation. Reproductive technologies create ethical dilemmas because treatment is not equally available to all people.

- **Beneficence**

Requires that the procedure be provided with the intent of doing good for the patient involved. Demands that health care providers develop and maintain skills and knowledge, continually update training, consider individual circumstances of all patients, and strive for net benefit.

- **Non-maleficence**

Requires that a procedure does not harm the patient involved or others in society. Infertility specialists operate under the assumption that they are doing no harm or at least minimizing harm by pursuing the greater good. However, because assistive reproductive technologies have limited success rates uncertain overall outcomes, the emotional state of the patient may be impacted negatively. In some cases, it is difficult for doctors to successfully apply the do no harm principle.

## **ETHICS**

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Ethics, also called moral philosophy, the discipline concerned with what is morally good and bad and morally right and wrong. The term is also applied to any system or theory of moral values or principles.

The terms *ethics* and *morality* are closely related. It is now common to refer to ethical judgments or to ethical principles where it once would have been more accurate to speak of moral judgments or moral principles. These applications are an extension of the meaning of ethics. In earlier usage, the term referred not to morality itself but to the field of study, or branch of inquiry, that has morality as its subject matter. In this sense, ethics is equivalent to moral philosophy.

Ethics or moral philosophy is a branch of philosophy that "involves systematizing, defending, and recommending concepts of right and wrong behavior." The field of ethics, along with aesthetics, concerns matters of value, and thus comprises the branch of philosophy called axiology.

Ethics seeks to resolve questions of human morality by defining concepts such as good and evil, right and wrong, virtue and vice, justice and crime. As a field of intellectual inquiry, moral philosophy also is related to the fields of moral psychology, descriptive ethics, and value theory.

Three major areas of study within ethics recognized today are:

1. Meta-ethics, concerning the theoretical meaning and reference of moral propositions, and how their truth values (if any) can be determined
2. Normative ethics, concerning the practical means of determining a moral course of action

3. Applied ethics, concerning what a person is obligated (or permitted) to do in a specific situation or a particular domain of action.<sup>[21]</sup>

## **BIOETHICS**

Bioethics is the study of typically controversial ethics brought about by advances in biology and medicine.

It is also moral discernment as it relates to medical policy, practice, and research.

Bioethicists are concerned with the ethical questions that arise in the relationships among life sciences, biotechnology, medicine, politics, law, and philosophy.

It also includes the study of the more commonplace questions of values ("the ethics of the ordinary") which arise in primary care and other branches of medicine.

The field of bioethics has addressed a broad swathe of human inquiry, ranging from debates over the boundaries of life (e.g. abortion, euthanasia), surrogacy, the allocation of scarce health care resources (e.g. organ donation, health care rationing) to the right to refuse medical care for religious or cultural reasons.

## **ETHICS COMMITTEE**

An ethics committee is a body responsible for ensuring that medical experimentation and human subject research are carried out in an ethical manner in accordance with national and international law.

An Ethics Committee is an independent body made up of a range of individuals including medical or scientific professionals and non-medical or non-scientific members (e.g. patients or lay members). An Ethics Committee may operate within an institution, or it may be national, or supranational or private.

Ethics committees have a responsibility to ensure the protection of the rights, safety and wellbeing of research participants, as well as assuring the public of that protection. It operates, among other things, expressing an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial, the adequacy of facilities, and on the methods and documents to be used to inform trial participants and obtain their informed consent. A trial should only begin when a favourable opinion by an Ethics Committee has been given.

Ethics Committees may also monitor studies once they have begun and once they are complete.

## **BENEFITS & RISKS OF BIOTECHNOLOGY**

Biotechnology is nearly as old as humanity itself. The food you eat and the pets you love? You can thank our distant ancestors for kickstarting the agricultural revolution, using artificial selection for crops, livestock, and other domesticated animals. When Edward Jenner invented vaccines and when Alexander Fleming discovered antibiotics, they were harnessing the power of

biotechnology. And, of course, modern civilization would hardly be imaginable without the fermentation processes that gave us beer, wine, and cheese!

When he coined the term in 1919, the agriculturalist Karl Ereky described 'biotechnology' as "all lines of work by which products are produced from raw materials with the aid of living things." In modern biotechnology, researchers modify DNA and proteins to shape the capabilities of living cells, plants, and animals into something useful for humans. Biotechnologists do this by sequencing, or reading, the DNA found in nature, and then manipulating it in a test tube – or, more recently, inside of living cells.

There are numerous discussions about the development and use of modern biotechnology, especially about the safety of genetically modified foods. Benefits for human health, as well as risks can be divided into four categories:

- 1. Benefits:**
- Increased food safety
  - Enhanced nutritional composition of foods
  - Food with even more health benefits
  - Reduction of certain chronic diseases related to diet

By the application of genetic engineering, organoleptic properties and expiration date of certain grains were able to improve. Delaying the rotting process of fruit and vegetables provides better quality, taste, color and texture. With the help of genetic engineering it is possible to create foods with greater amount of minerals, vitamins and antioxidants. Also, by increasing crop yields deforestation is prevented, and, the most important for the developing countries, economic development is accelerated.

For developing countries, particularly useful is growing beans resistant pathogens, virus-resistant papaya, cotton, and rice enriched with vitamin A. The production of certain vaccines for oral use is also important, which would be cheaper, easier to store and less stressful to use than the previous ones, and would be used for prevention of diarrhea, cholera and hepatitis B.

On the other hand, for many researchers, and the public production of so-called Frankenstein food is unacceptable tampering with nature.

## **2. Risks:**

- Allergies
- Toxicity
- Nutrient imbalance

- Decrease of food diversity

There are concerns that the use of genetic engineering in the food industry can increase sensitivity to certain allergens. In fact, the transfer of allergenic properties of donor can be transferred to recipient. Foreign genes can disrupt the balance of nutrients. The question is how that changes will affect:

- Interaction of nutrients
- Interaction between nutrients and genes
- Bioavailability of nutrients
- Metabolism and
- "Strength" of nutrients.

By the production of genetically modified foods, different genes from different genetically modified organisms are transmitted in different ways. So far, this food is present in the market, because it is approved in many studies, so it is a little likely to endanger the life of man.

In order to determine the attitude to genetically modified products, we need to have in mind many facts, such as the rapid growth in world population, the available farmland, environment and the characteristics of genetically modified food and its impact on human health. At the same time it takes extensive knowledge and multidisciplinary approach to this issue in order to take advantage of this technology, and to avoid negative consequences.

#### **Methods of resolving ethical issues of biotechnology:**

1. We need to understand what might be called the nature of genes and their origins, evolution, and their role in the shaping of different organisms
2. Until we understand well the size and role of genetic exchange between different types of materials we should not experiment with transgenic organisms
3. We must bear in mind that the largest number of phenotype properties of humans by which people differ, result from the large number of genes and environmental factors
4. Information related to the genetics should exclusively be used to allow each person to make a personal decision about life style.
5. The creation of biological weapons should be completely banned
6. Genetic diversity of species on Earth is one of the main resources of our planet and it is of the greatest interest to preserve that diversity.

#### **ETHICAL AND SOCIAL ISSUES IN GENE THERAPY**

The biology of human gene therapy is very complex, and there are many techniques that still need to be developed and diseases that need to be understood more fully before gene therapy can

be used appropriately. In addition, because gene therapy involves making changes to the body's genetic setup, it raises many unique ethical concerns. Scientific and ethical discussions about gene therapy began many years ago, but it was not until 1990 that the first approved human gene therapy clinical trial was initiated. This clinical was considered successful because it greatly improved the health and well-being of the few individuals who were treated during the trial. However, the success of the therapy was tentative, because along with the gene therapy the patients also continued receiving their traditional drug therapy. This made it difficult to determine the true effectiveness of the gene therapy on its own, as distinct from the effects of the more traditional therapy.

Measuring the success of treatment is just one challenge of gene therapy. Research is fraught with practical and ethical challenges. As with clinical trials for drugs, the purpose of human gene therapy clinical trials is to determine if the therapy is safe, what dose is effective, how the therapy should be administered, and if the therapy works. Diseases are chosen for research based on the severity of the disorder (the more severe the disorder, the more likely it is that it will be a good candidate for experimentation), the feasibility of treatment, and predicted success of treatment based on animal models. This sounds reasonable. However, imagine you or your child has a serious condition for which no other treatment is available. How objective would your decision be about participating in the research?

How do researchers determine which disorders or traits warrant gene therapy? Unfortunately, the distinction between gene therapy for disease genes and gene therapy to enhance desired traits, such as height or eye color, is not clear-cut. No one would argue that diseases that cause suffering, disability, and, potentially, death are good candidates for gene therapy. However, there is a fine line between what is considered a "disease" (such as the dwarfism disorder achondroplasia) and what is considered a "trait" in an otherwise healthy individual (such as short stature). Even though gene therapy for the correction of potentially socially unacceptable traits, or the enhancement of desirable ones, may improve the quality of life for an individual, some ethicists fear gene therapy for trait enhancement could negatively impact what society considers "normal" and thus promote increased discrimination toward those with the "undesirable" traits. As the function of many genes continue to be discovered, it may become increasingly difficult to define which gene traits are considered to be diseases versus those that should be classified as physical, mental, or psychological traits.

To date, acceptable gene therapy clinical trials involve somatic cell therapies using genes that cause diseases. However, many ethicists worry that, as the feasibility of germ line gene therapy improves and more genes causing different traits are discovered, there could be a "slippery slope" effect in regard to which genes are used in future gene therapy experiments. Specifically, it is feared that the acceptance of germ line gene therapy could lead to the acceptance of gene therapy for genetic enhancement. Public debate about the issues revolving around germ line gene therapy and gene therapy for trait enhancement must continue as science advances to fully appreciate the appropriateness of these newer therapies and to lead to ethical guidelines for advances in gene therapy research. Major participants in the public debate have come from the fields of biology, government, law, medicine, philosophy, politics, and religion, each bringing different views to the discussion.



## **ETHICS IN ANIMAL EXPERIMENTATION**

In order to prevent undue suffering, ethical considerations in animal studies are important. Generally, before experiments on animals are conducted, the research protocol must be reviewed by animal ethics committees. The guiding principle of these committees is usually the 3 Rs.

- First, animal experiments must be replaced wherever possible by other methods such as mathematical modeling, or an *in vitro* biological system.
- Second, there must be a reduction in the number of animals used. Only the number required to obtain reliable data must be used in an experiment. A thorough literature search must be done beforehand to prevent duplicating experiments.
- Third, the study must be refined to minimize its overall impact on the animals used.

There should also be a local animal care committee which ensures that the animals are housed in appropriate facilities. The committee should also determine if animals are needed to test the hypotheses listed. If so, the animal care committee should also determine the appropriate sample sizes and procedures to be used in the experiment. The animals should have access to veterinary care. All personnel who work with the animals should be sufficiently trained in both the experimental procedure and ethical handling of the animals.

Legislation of animal experimentation is based on the idea that it is morally acceptable to conduct these experiments under certain conditions. This illustrates the importance of research ethics which is what drives how these animals should be treated. This includes having a clear rationale for why a hypothesis needs to be tested using animals. There should be a reasonable expectation that the experiment will generate useful data. The study design should also seek to minimize the number of animals used in the experiment while still being statistically appropriate.

All researchers handling the animals used for experimentation should also be trained in handling the particular species in the study. Their pain or discomfort should be minimized. Anesthesia should be used as required and repeated surgical procedures on the same animal should be avoided wherever possible. The humane treatment of the test animals should be incorporated into the study protocols and aseptic techniques should be used whenever possible. Only skilled personnel should perform surgical procedures and anesthetization of the animals in the study.

The national centre for the replacement, refinement, and reduction of animals in research (NC3Rs) has issued ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines are intended to improve the reporting of research using animals. This checklist provides information that needs to be provided in the different section of the manuscript such as experimental animals, study design, experimental procedures, housing and husbandry, ethical statements, and more.

## **ETHICAL ISSUES IN ABORTION**

Abortion is one of the controversial issues discussed in medical ethics. Abortion is advocated by the persons who have themselves been born. Abortion is a human right issue because human

beings have a right to life. When does a person begin to exist is a moral issue. By all the criteria of modern molecular biology, life is present from the moment of conception. First step in the evolution of ethics is the solidarity with the other human being

The opponents of abortion argue as follows:

Fetus has to be regarded as human being

Killing an innocent human being is morally wrong

Aborting is an example of killing and terminating a human being's life.

So, being engaged in aborting is morally wrong. If one is adamantly opposed to abortion, one is committed to some set of values, which requires that women who become pregnant (whether intentionally or unintentionally) must endure the process of pregnancy and birth, no matter how distressing, painful and risky it is for them. The justification given for this is usually based on an abstract notion of the value of 'fetal life', rather than on the ground that suffering is morally improving for the women concerned. Extreme opponents of abortion argue that abortion is equivalent to murder and that, no matter how much women may suffer, they cannot be allowed to 'kill their children'. Termination of pregnancy brings out conflicts of right between two persons, the right of mother and the right of child in womb. Has the mother right to have the child in the womb destroyed? Does that the unborn child have right of life? Has the doctor right to kill the child in the womb at the request of the mother

Abortion is inherently different from other procedures because no other procedure involves the purposeful termination of potential life. If the fetus is a person, then it has the rights that belong to persons, including right to life. The concept of person-hood, in other words is the bridge that connects the fetus with the right to life . Thus, in the system of human rights, there is often a need to balance rights against each other. The right to the life of the mother and the same right of the fetus.

### **Euthanasia**

Euthanasia is the termination of a very sick person's life in order to relieve them of their suffering.

A person who undergoes euthanasia usually has an incurable condition. But there are other instances where some people want their life to be ended.

In many cases, it is carried out at the person's request but there are times when they may be too ill and the decision is made by relatives, medics or, in some instances, the courts.

The term is derived from the Greek word *euthanatos* which means easy death.

The issue has been at the centre of very heated debates for many years and is surrounded by religious, ethical and practical considerations.

### **The ethics of euthanasia**

Euthanasia raises a number of agonising moral dilemmas:

- is it ever right to end the life of a terminally ill patient who is undergoing severe pain and suffering?
- under what circumstances can euthanasia be justifiable, if at all?
- is there a moral difference between killing someone and letting them die?

At the heart of these arguments are the different ideas that people have about the meaning and value of human existence.

Should human beings have the right to decide on issues of life and death?

There are also a number of arguments based on practical issues.

Some people think that euthanasia shouldn't be allowed, even if it was morally right, because it could be abused and used as a cover for murder.

### **Killing or letting die**

Euthanasia can be carried out either by taking actions, including giving a lethal injection, or by not doing what is necessary to keep a person alive (such as failing to keep their feeding tube going).

### **'Extraordinary' medical care**

It is not euthanasia if a patient dies as a result of refusing extraordinary or burdensome medical treatment.

### **Euthanasia and pain relief**

It's not euthanasia to give a drug in order to reduce pain, even though the drug causes the patient to die sooner. This is because the doctor's intention was to relieve the pain, not to kill the patient. This argument is sometimes known as the Doctrine of Double Effect.

### **Mercy killing**

Very often people call euthanasia 'mercy killing', perhaps thinking of it for someone who is terminally ill and suffering prolonged, unbearable pain.

## **Why people want euthanasia**

Most people think unbearable pain is the main reason people seek euthanasia, but some surveys in the USA and the Netherlands showed that less than a third of requests for euthanasia were because of severe pain.

Terminally ill people can have their quality of life severely damaged by physical conditions such as incontinence, nausea and vomiting, breathlessness, paralysis and difficulty in swallowing.

Psychological factors that cause people to think of euthanasia include depression, fearing loss of control or dignity, feeling a burden, or dislike of being dependent.

## **Ethical problems of euthanasia**

Does an individual who has no hope of recovery have the right to decide how and when to end their life?

## **Why euthanasia should be allowed**

Those in favour of euthanasia argue that a civilised society should allow people to die in dignity and without pain, and should allow others to help them do so if they cannot manage it on their own.

They say that our bodies are our own, and we should be allowed to do what we want with them. So it's wrong to make anyone live longer than they want. In fact making people go on living when they don't want to violates their personal freedom and human rights. It's immoral, they say to force people to continue living in suffering and pain.

They add that as suicide is not a crime, euthanasia should not be a crime.

## **Why euthanasia should be forbidden**

Religious opponents of euthanasia believe that life is given by God, and only God should decide when to end it.

Other opponents fear that if euthanasia was made legal, the laws regulating it would be abused, and people would be killed who didn't really want to die.