

BIOSAFETY AND BIOETHICS

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Biosafety

- Biosafety is defined as prevention of large scale loss of Biological integrity with focuses both on ecology and human health
- It is a system of handling of toxic and dangerous biological and chemical substances

Components of safety

- Safe handling, Storage and Disposal of Specimens, Chemicals, Instruments, Radioactive components and Fire and electrical safety
- Disasters management for natural calamities like Earthquakes, Hurricanes etc.

Technical Terms

Biohazard: An agent of biological origin that has the capacity to produce deleterious effects on human

That may be Microorganisms and/ or Toxins, allergens developed from them or Toxins and /or allergens developed from higher plants and animals

Biosafety: The containment (Inhibitory) principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins and their accidental release

Biosecurity: Control of accidental or deliberate release of biohazardous materials

Containments (Inhibitions)

- The term Containment is used to describe the safe methods of managing infectious agents in laboratory environments where they are being handled and maintained
- To reduce the exposure of laboratory workers and other persons to hazardous environment

Elements of Containments:

- Laboratory Practice and Techniques
- Safety Equipment (Primary Barriers)
- Design facility (Secondary Barriers)

Types of Containments

1. Physical Containments: Physical methods adopted in laboratory for preventing the escape of GEOs to the environment

Ex. Air filters, Sterilization lights, Waste disposal and Protective handling

2. Biological Containments: Biological Principles used to prevent the escape of GEOs and Microbes

Ex. Conditions make the organism unable to survive outer environment

Some unfortunate examples.....

1950-Typhoid fever

2003 -2014: Large outbreaks of SARS, Ebola, Dengue

1980 : Large outbreaks of Hepatitis, Tuberculosis

2019: Corona pandemic through out the world

Need of Biosafety

- **To support the medical and scientific research on microbes and the human immune response to them**
- **To apply such research to the discovery and development of vaccines, drugs and diagnostic tests to designed to protect the general population**
- **To insure that the every has sufficient research facilities to carry out these activities**

Scope of Biosafety

- **Academic Research in the field of:**

- ✓ **Ecology**
- ✓ **Medicine**
- ✓ **Chemistry**
- ✓ **Agriculture**
- ✓ **Exobiology**

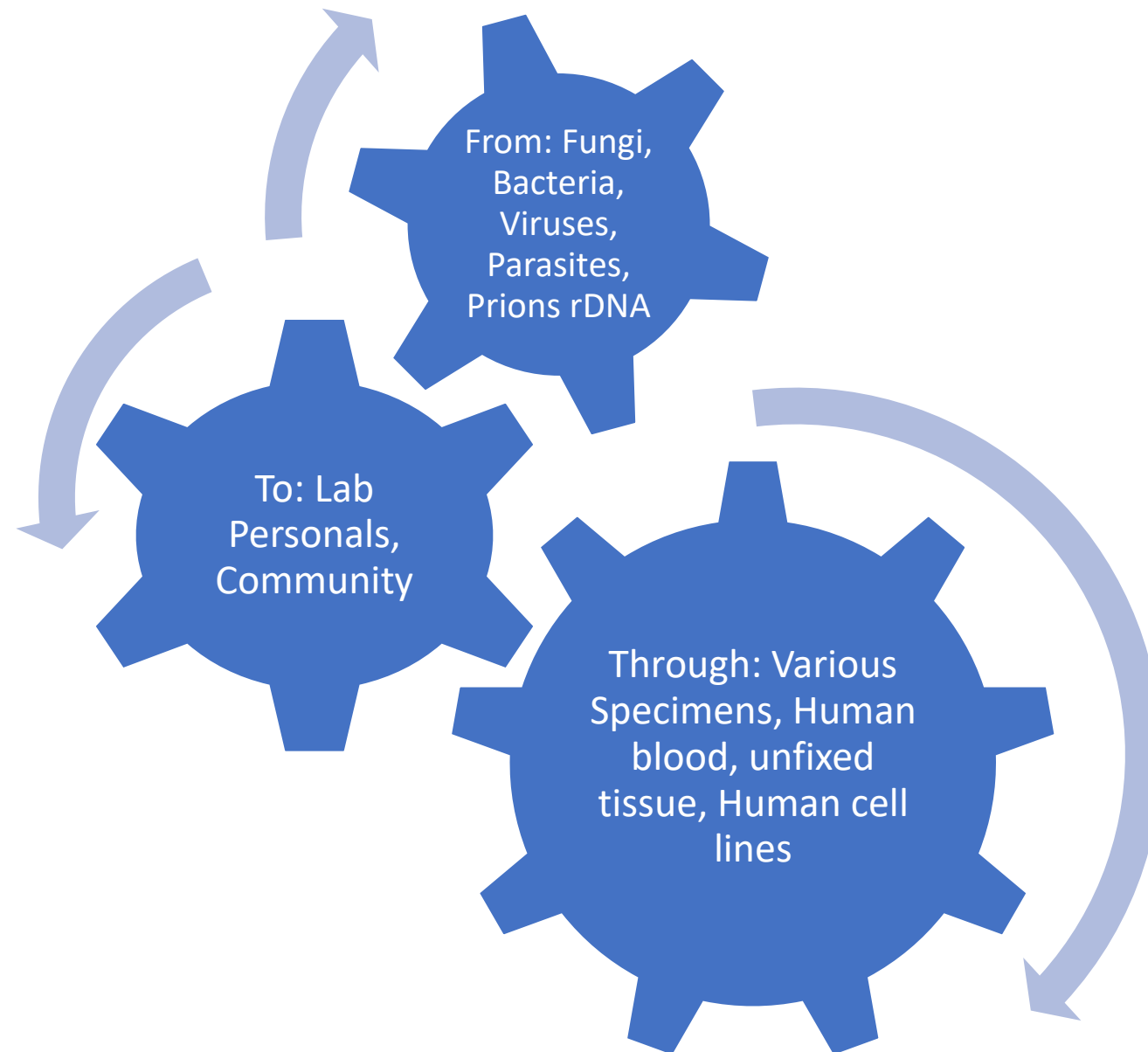
For providing advice on laboratory design, risk assessment of experiments involving infectious agents and in vivo and in vitro rDNA studies

Biosafety Issues

- **Laboratory safety**
- **Blood born Pathogens (BBP)**
- **Recombinant DNA (rDNA) and production of genetically modified food and organisms**
- **Biological waste disposal**
- **Shipping of infectious substances and diagnostic specimen**

Areas of Risks

- **Risk for health:** Toxicity, Allergies, Pathogen drug resistance (Antibiotic resistance)
- **Risk for Environment:** Persistency of transgene elements and products, susceptibility to nontarget organisms and unpredicted expressions
- **Risk in Agriculture:** Resistance/ Tolerance of target organisms, production of weed or super weed, Alteration of nutritional value
- **Risk of interaction with non target organisms:** Genetic pollution, Horizontal gene transfer, Generation of new line viruses
- **General concerns:** Hight cost requirements, Loss of familiarities, Ethical issues



Risk Groups

- **RG 1: Agents not associated with diseases in healthy humans**
- **RG 2: Agents associated with rare human diseases**
- **RG 3: Agents associated with serious and lethal human diseases**
- **RG 4: Agents associated with serious and lethal human diseases for which preventive measures are not available**

Biosafety Levels (BSL)

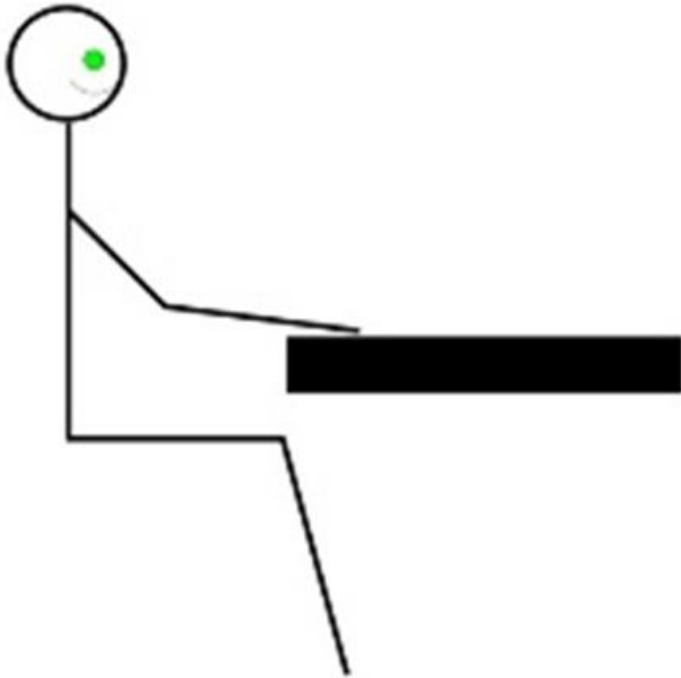
- It refers to classification system used to indicate the safety precautions required for known to be dangerous or lethal experiments
- It is a level of bio-containment precautions required to undertake while handling of hazardous biological agents in an enclosed facility through a combination of safeguards including
 - ✓ Engineering control
 - ✓ Management policies
 - ✓ Standard work practice

- **BSL 1:** Work with least dangerous agents and require fewest precautions
- **BSL 2:** Agents associated with human diseases
- **BSL 3:** Agents causing serious diseases transmitted by inhalation for which immunization and antibiotic treatment is available
- **BSL 4:** Agents causing serious diseases for which known treatment and immunization is not available

Barriers

- **Primary Barriers:** Physical barriers like personal protective equipment and breathing apparatus
- **Secondary Barriers:** Safe laboratory structural aspects, sinks for handwash, air exhausts and sterilization equipment and Staff immunization with TB, Rubella, Typhoid, Anthrax, Poliomyelitis and Diphtheria

BL1



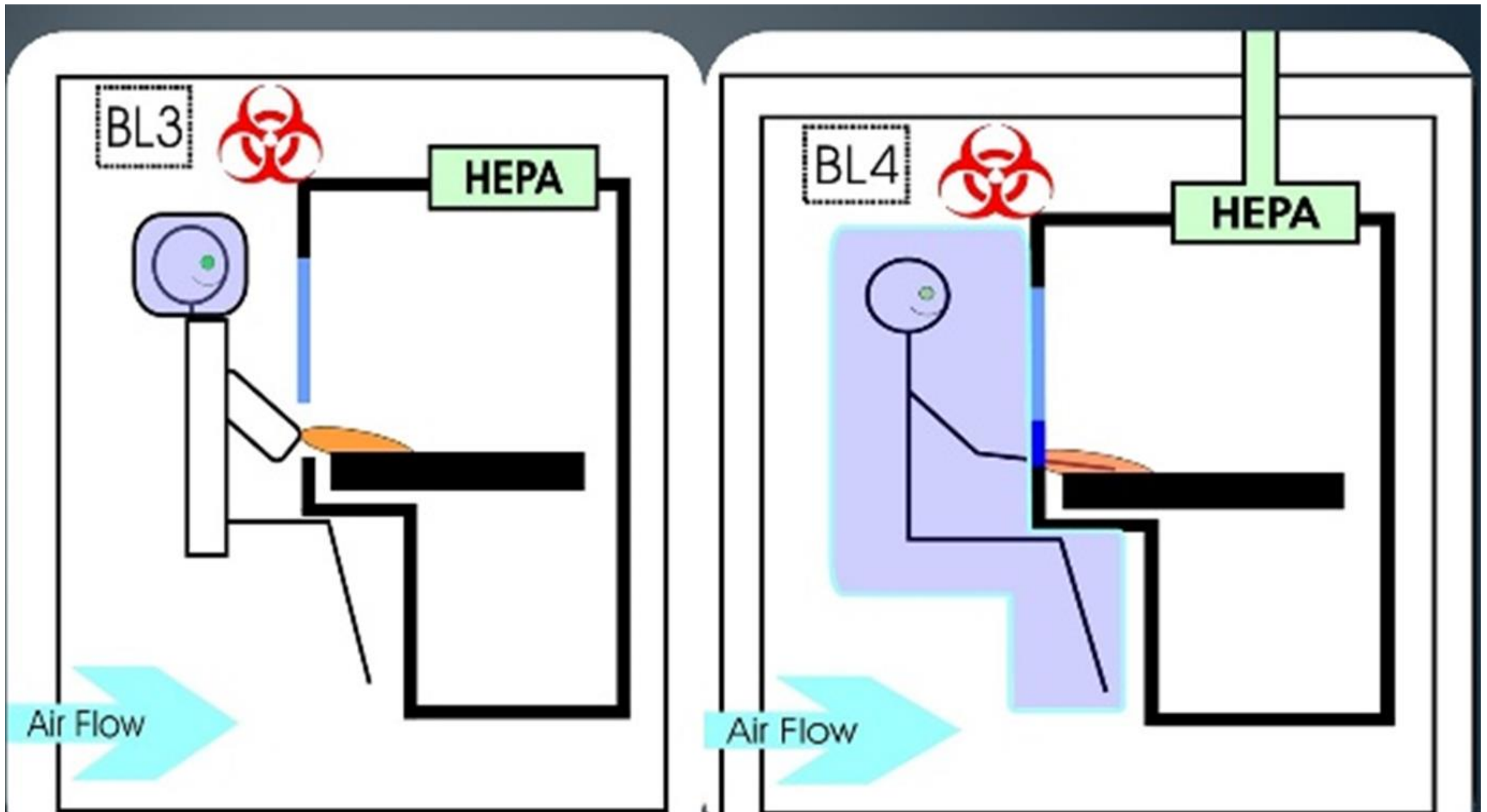
BL2



HEPA



Air Flow



Biosafety Cabinets (BSC)



REMEMBER:

The main purpose of a BSC is to **protect you and the environment** from exposure to biohazards while working with infectious agents

In addition, Class II and III BSCs will protect your research materials from airborne contaminants with the aid of HEPA supply filters

RG 1 Agents

- **E.coli**
- **Transgenic Plants**
- **Plasmids**
- **Fungi**
- **Yeast**

BSL 1 Practice

- **Bench top work**
- **Daily Decontamination**
- **Manual pipetting**
- **Proper handwashing**
- **Red bag waste**
- **Safety glasses, gloves and lab coats**
- **Standard Microbiological practice**

RG 2 Agents

- **Human and Primate cells**
- **Herpes Simplex Virus**
- **Attenuated human immunodeficiency virus**
- **Hepatitis B virus**
- **Salmonella, Clostridium**
- **Patient specimens like blood, body fluids and infected tissues**

BSL 2 Practice

- **Limited access to lab**
- **Daily decontamination**
- **Mechanical pipetting**
- **Red bag waste**
- **Safety glasses, gloves and lab coats**

RG 3 Agents

- **Human immunodeficiency virus**
- **Mycobacterium tuberculosis**
- **Coxiella burnetii**

BSL 3 Practice

- **No public access**
- **Daily decontamination**
- **Foot activated handwashing sinks**
- **No sharp containers**

RG 4 Agents

- **Highly contagious viruses like Ebola, Herpes B, Lassa fever virus, Corona virus**

BSL 4 Practice

- **All facilities of BSL 3**
- **Maximum containment facilities**
- **Chemical decontamination showers**
- **Class III biosafety cabinets**
- **Waste liquid collection and decontamination**

Aim of Biosafety guidelines

- **Regulation of rDNA research with organisms that have no or limited adverse effects**
- **Minimizing the possibilities of occasional release of GEOs from the laboratory**
- **Banning the release of GEOs if they are supposed to be causing potential risk in the environment**

rDNA Biosafety Guidelines of India

- **Policy proposed or Adopted by the Government to avoid the risks of GEOs on Environment and Public Health**
- **The Recombinant DNA Safety Guidelines proposed by DBT in 1983 which were amended in 1990**

The Guidelines deals with a set of rules for hazardous organisms for:

- ✓ **Production**
- ✓ **Use**
- ✓ **Import**
- ✓ **Export**
- ✓ **Storage**

Committees for rDNA guidelines implantation in India

- **Institutional Biosafety Committee (IBSC):** Controls research activities at institutional level
- **Review Committee on Genetic Manipulation (RCGM):** Reviews for situation for research on Hazardous organisms and grants permission to work and provide advice on IPR and Patents
- **Genetic Engineering Approval Committee (GEAC):** It approved the GEOs for large scale production and use

Activities need to acquire permission and Approval

- **Toxin gene cloning and transfer in plants**
- **Cloning of genes for Vaccine production**
- **Cloning of Antibiotic Resistance gene**
- **Cloning of Oncogenes**
- **Experiments with infectious animals**
- **Experiments with Plant Viruses**
- **Transgenesis experiments with animal cell cultures**
- **Gene therapy for hereditary diseases**

Ethics and Morals

- Study of Ethical and Moral effects of new biological discoveries and biomedical advances
- The term Bioethics was first introduced by **Van Rensselaer Potter in 70s for protection of Biosphere**
- It was later used to refer to study of the ethical issues arising from health care, biological and medical sciences

Ethics Vs Moral

- It is concern with right or wrong conduct
 - Guides to behaviour
 - Making choice or Judgement
-
- ✓ Morels are individual frame work for decision making
 - ✓ Ethics are generalized conceptual frame work for decision making

Moral Considerations in Ethics

- Whether one ought to act to maximize the best outcomes
- Are we required only not to harm others or must we also act in ways that benefit them or make their lives better?
- What should be done when we think policies or law are unethical
- How could we access that all people have a fair or maybe an equal opportunity
- How and when should we share information about a medical treatment to best permit others

Bioethics

- **Bioethics concerns itself with issues in healthcare, medicine, research, biotechnology, and the environment**
- **Professionals working in the field of bioethics include philosophers, scientists, health administrators, lawyers, anthropologists and social workers**
- **Each field contributes important insights, resources and methodologies and efforts to think about or make changes to practices and policies that raise ethical concerns**

Bioethics in Biotechnology

- **Bioethics also needs to address emerging biotechnologies that affect basic biology and future humans**

These developments include:

- **Gene Cloning**
- **Gene therapy**
- **Human genetic engineering**
- **Manipulation of basic Animal and Plant biology through altered DNA, RNA and proteins**

However the use of this technology has raised some concerns, which include:

- a. Their ecological impact**
- b. Their potential harm to human health**
- c. Their negative impact due to development of resistance**
- d. Their contribution to corporate monopoly**

So, there is a need to address life through Ethical point of views

Principles of Bioethics

- **Autonomy:** Right of self determination and ability to take decisions independently
- **Beneficence (Kindness):** To do well, to promote well being and work for the benefit of others
- **Non maleficence:** To do no harm or to avoid doing harm
- **Justice:** Treat every one alike and consider the equity

One more.....

- **Openness:** Not to keep the information secret

Scope of Bioethics

- **Human genome projects**
- **Stem cell research**
- **Artificial reproductive technologies**
- **Pre-implementation diagnosis**
- **The synthesis of new life forms**
- **The possibilities of successful reproductive cloning**

Major Issues of Bioethics

- **Eugenics: DNA manipulation for improvement of human race**

Advancement of species
and extinction of certain
genetic diseases



Lead to discrimination of
races and possibilities of
eradication of race

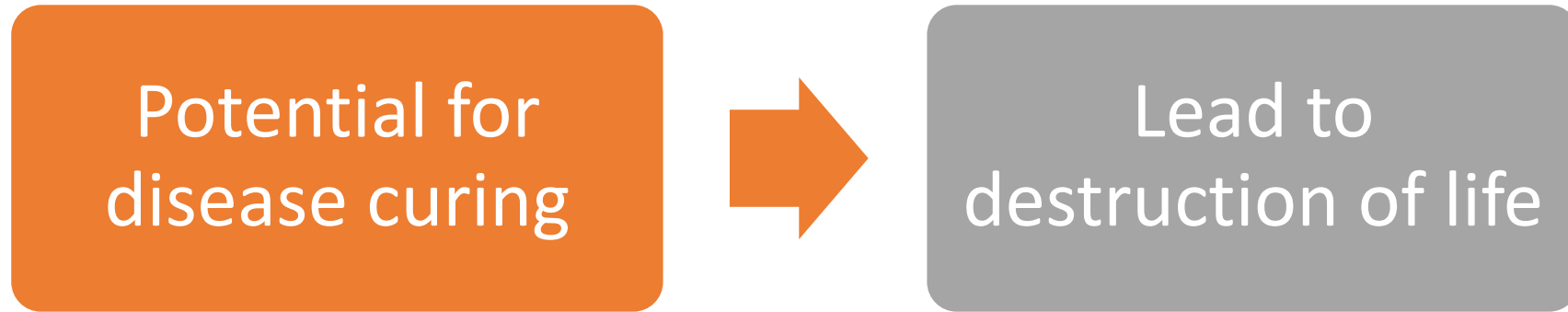
- **Human cloning: Scientific production of identical human cell, tissue and entire body**

Development of
regenerative medicines,
tissue and organ donation

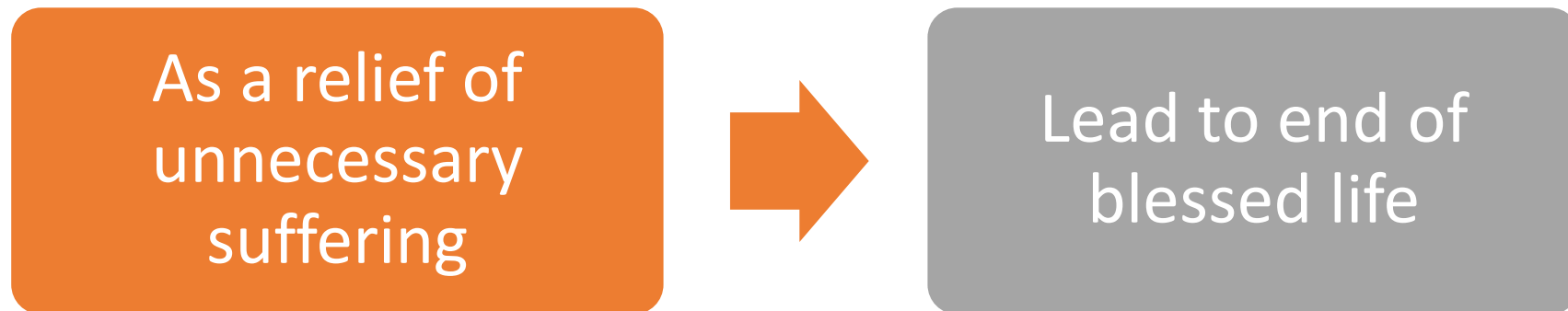


Lead to human farming
and killing the clones for
body parts

- Stem cell research: Differentiation of stem cell into a range of specialized cell types



- Euthanasia: Purposefully ending a life



Thank You.....