RESEARCH ETHICS

What is meant by Ethics?

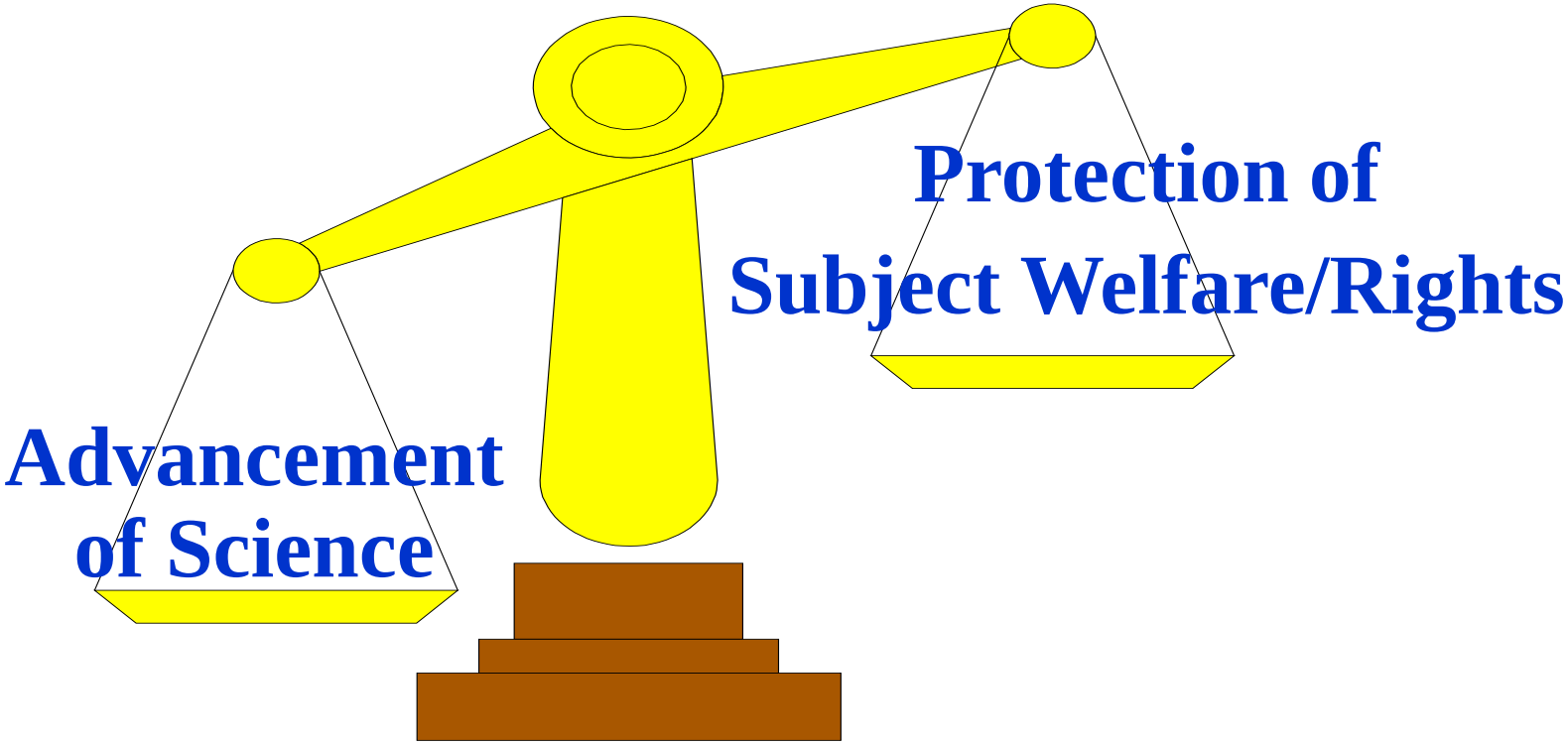
“Moral principles that govern a person's behaviour or the conducting of an activity”

Or

“The branch of knowledge that deals with moral principles or codes of conduct”

Each **individual scientist** has the ***ethical responsibility*** to seek knowledge and to strive to improve the quality of life.

BALANCING TWO GOALS



HISTORICAL EXAMPLES OF UNETHICAL RESEARCH

NAZI MEDICAL EXPERIMENTS (1933-1945)

-- It was a series of medical experiments on large numbers of **prisoners**, including children, by Nazi Germany in its concentration camps in the early to mid-1940s, during World War II.

-- Typically, the experiments resulted in **death**, **trauma**, **disfigurement** or **permanent disability**, and as such are considered examples of **medical torture**.

-- After the war, these crimes were tried at what became known as the **Doctor's Trial**, and led to the development of the **Nuremberg Code of medical ethics.**

Japanese germ warfare

-- **Unit 731** was a secret **biological** and **chemical** warfare research and development unit of the **Imperial Japanese Army** that undertook lethal human experimentation during the **Second Sino-Japanese War (1937–1945)**.

-- Some historians estimate that up to **250,000** men, women, and children were subjected to experimentation conducted by Unit 731.

-- Instead of being tried for war crimes, the researchers involved in Unit 731 were **secretly given immunity** by the U.S. in exchange for the data they gathered through human experimentation.

International Codes of Medical Ethics

Nuremberg Code

-- The **Nuremberg Code** is a set of **research ethics principles** for human experimentation set as a result of the Nuremberg (Germany) trials at the end of the Second World War.

-- In May, 1947 **Dr. Leo Alexander** had submitted to the Counsel for War Crimes **six points** defining legitimate medical research.

The trial verdict adopted these points and **added four**. The **ten points** constituted the "Nuremberg Code".

These are:

1. Required is the **voluntary, well-informed, understanding consent** (agreement) of the human subject in a **full legal capacity**.

2. The experiment should aim at **positive results for society** that cannot be procured in some other way.

3. It should be **based on previous knowledge** (like, an expectation derived from animal experiments) **that justifies the experiment.**

4. The experiment should be set up in a way that **avoids unnecessary physical and mental suffering and injuries.**

5. It **should not be conducted** when there is any reason to believe that it **may have a risk of death or disabling injury**.

6. The **risks of the experiment** should be **in proportion** to (that is, not exceed) the **expected humanitarian benefits.**

7. **Preparations and facilities must be provided** that **adequately protect** the subjects against the experiment's risks.

8. The **staff** who conduct or take part in the experiment must be **fully trained and scientifically qualified**.

9. The human subjects must be **free to immediately quit the experiment at any point** when they feel physically or mentally unable to go on.

10. Likewise, the **medical staff must stop the experiment at any point** when they observe that continuation would be dangerous.

Belmont Report

The **Belmont Report** issued on 30 September 1978 at Belmont Conference Center is a report created by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, USA.

It summarizes ethical principles and guidelines for research involving human subjects.

The three fundamental ethical principles for using any human subjects for research are:

1. Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception;
2. Beneficence: The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects; and
3. Justice: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to *potential* research participants — and equally.

Three primary areas of application are also stated.

These are:

1. informed consent
2. assessment of risks and benefits
3. selection of subjects

CIOMS

-- The **Council for International Organizations of Medical Sciences (CIOMS)** is an international nongovernmental organization established jointly by WHO and UNESCO in 1949.

-- CIOMS serves the scientific interests of the international **biomedical community** in general and has been active in providing guidelines for the ethical conduct of research, among other activities.

-- CIOMS promulgated guidelines in 1993 entitled *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

-- There are **15 guidelines** addressing issues such as informed consent, standards for external review, recruitment of participants, and more.

Informed Consent

Informed consent concern subjects' willing participation in research in which they have **full understanding** of the study before the study begins.

The principal means for ensuring that the **rights of research subjects** are protected is through **informed consent.**

Major Elements of Informed Consent

1. Researcher is identified and credentials presented.
2. Subject selection process is described.
3. Purpose of study is described.
4. Study procedures are discussed.
5. Potential risks are described.

6. Potential benefits are described.

7. Compensation is discussed.

8. Alternative procedures, if any, are disclosed.

9. Anonymity or confidentiality is assured.

10. Right to refuse or to withdraw from study without penalty is offered.

Documentation Of Informed Consent

Informed Consent for
Oral & Maxillofacial Surgery

Procedure: Extraction (removal) of teeth_____.

Alternatives to Surgery: I understand that if this tooth/teeth is/are not removed, my condition may worsen, resulting in complications including but not limited to:

1. Infection
2. Loss of additional teeth
3. Pain

Possible complications which have been explained to me are:

1. Dry socket
2. Infection
3. Decision to leave a small piece of root in the jaw when its removal would require extensive surgery and increased risk of complications.
4. Bleeding and bruising
5. Swelling
6. Injury to adjacent teeth or fillings
7. _____

I have had the opportunity to discuss this surgery with the doctor and to ask questions. I consent to the surgery as described.

_____ _____

Patient, Parent or Guardian Date

_____ _____

Doctor Witness

Assent

When children are **younger than 7 years**, **parental consent is sufficient**.

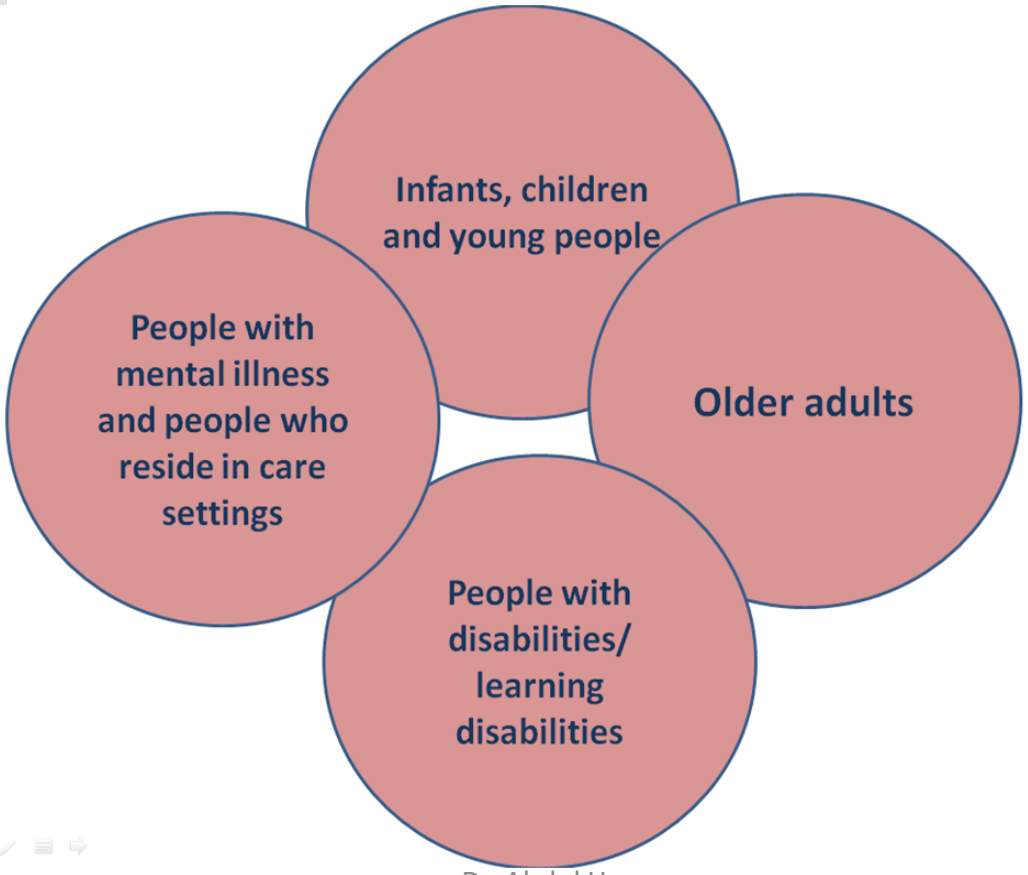
If a child is **older than 7 years**, not only must the **parent consent to the child's participation** but the **child must also agree** to be in the study by giving assent to participate in a study.

Assent means that an underage child or adolescent freely chooses to participate in a study.

-- The researcher has the responsibility to protect the **privacy and the dignity** of the people involved in the research.

-- The researcher has an obligation not to perform such research study that involves **undue physical risks, psychological risks,** or **both.**

Vulnerable Research Subjects



RESEARCH MISCONDUCT

- FABRICATION
- FALSIFICATION
- PLAGIARISM

Fabrication:

The action or process of manufacturing or inventing a false story

Falsification:

It is to present false data as true.

Plagiarism:

It is the practice of taking someone else's work or ideas and passing them off as one's own

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CONCLUSION

- **If research is based on a robust design and in a safe and ethical manner, it can be of benefit to all**
- **Professional codes, laws, regulations, and ethics committees can provide guidance *but* *ultimate determinant rests with researcher's value system and moral code***


Thank You!