Ethical Issues in Research Work

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Objectives

At the end … you should have knowledge about ..

- Ethics , Definition of ethics
- Development of Ethical Codes
- Main pillars of the ethical aspect
- Importance of ethics in research

What is Ethics

- **ETHICS-Greek word:**
- **ethos=custom or convention, or the spirit of community**
- **Research may influence patient care standards .. How??**
- **Professionals are obliged to ensure safe, robust and ethical research.**

Definition

- Ethics is defined as the moral principles that govern the professional conduct **concerning the rights and duties of researchers**, their patients, and their fellow practitioners, as well as their actions in the care of patients and in relations with their families. That concerned with distinguishing **between right and wrong human actions.**

Development of Ethical Codes

- Atrocious, unethical activities implemented in Europe from 1933-1945

EXAMPLES OF UNETHICAL "RESEARCH"

- Criminal and unscientific behavior of physicians in concentration camps in Nazi Germany – led to adoption of Nuremberg Code (1947).
- 1936 – U.S. Public Health Service started study of effects of untreated syphilis in Tuskegee, AL long after effective treatment for the disease was known.
- 1963- Jewish Chronic Diseases Hospital – 22 elderly patients injected with cancer cells without their knowledge to test immunological response.
- Willowbrook State Hospital, NY: retarded children deliberately infected with viral hepatitis to study natural history.

TUSKEGEE SYPHILIS STUDY(1932)

JEWISH CHRONIC DISEASE HOSPITAL STUDY (1960)

Development of Ethical Codes

- Nuremberg code, 1947
- Helsinki Declaration 1965, rewritten 1975-WHO
- Council for international organizations of medical sciences.. 2002
- In all universities, organizations and research agencies, there should be an ethical committee. No research can be implemented before getting the approval from the ethical committee.

INSTITUTIONAL ETHICAL COMMITTEE

- Committee that reviews research to ensure that the investigator is conducting research ethically
- Consists of at least five members from different background
- IRC in hospitals composed of physicians, lawyers, clergy, community and lay persons and more recently nurses.

GUIDELINES FOR CRITIQUING ETHICAL ASPECTS OF STUDY

- Were participants subjected to any physical harm or psychological distress?
- Did the benefits outweigh potential risks?

Was any type of coercion or undue influence used to recruit participants?

Were the participants deceived in any way?

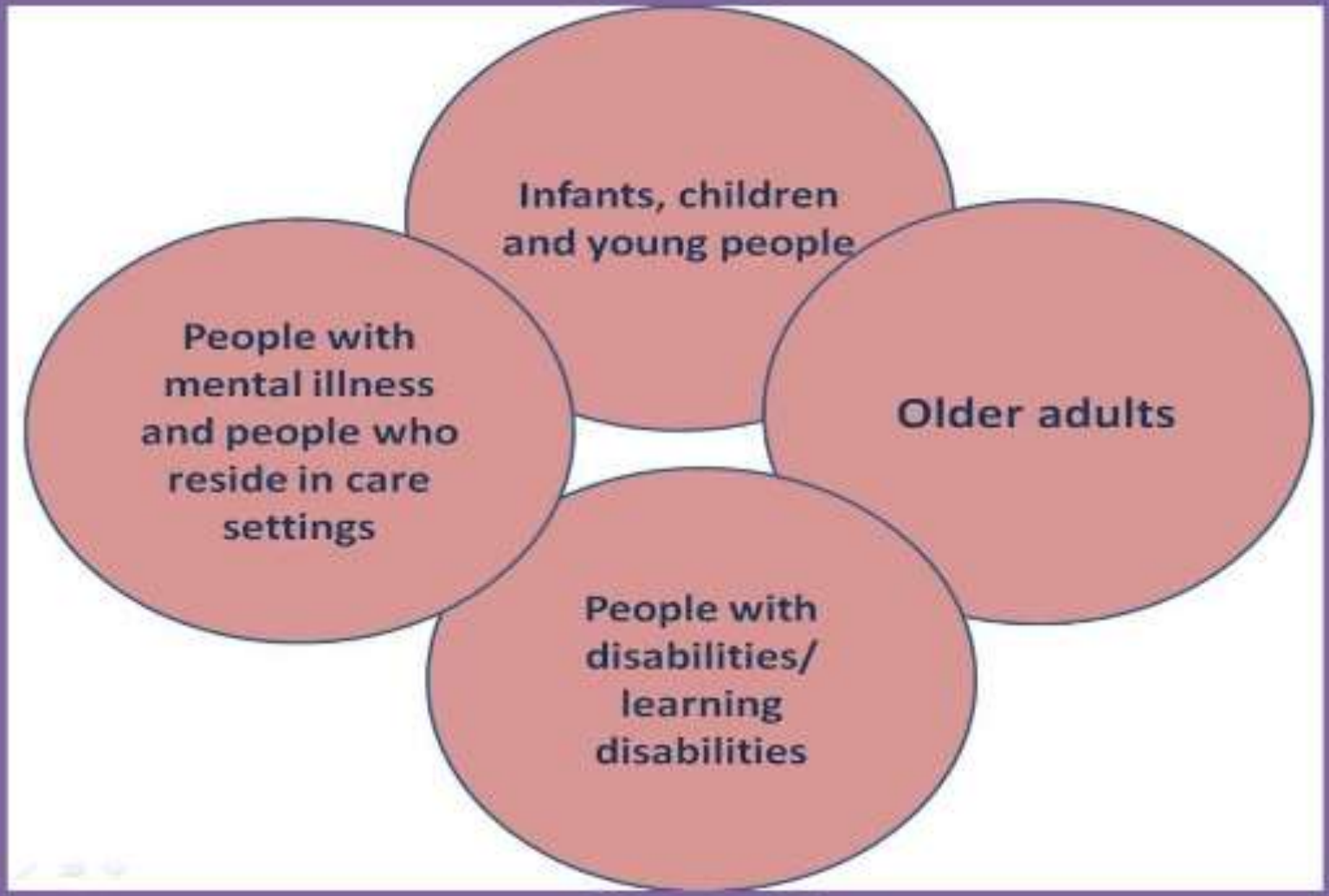
Were ***appropriate informed consent procedures*** used?

Were adequate steps taken to safeguard participant's privacy?

Were ***vulnerable groups*** involved in research?

Were groups omitted from the inquiry without a justifiable rationale?

VULNERABLE SUBJECTS



IMPORTANCE OF ETHICS IN RESEARCH

Protects the **vulnerable groups** and other study participants from exploitation

Establishes risk-benefit ratio for study subjects.

Builds capability of subjects to accept or reject participation in study .. ***appropriate informed consent***

- Ensures fullest respect.. no Bias, Concealment, Deception .. Preserve dignity, privacy, and fair treatment (justice) for all.

- Pharmaceutical companies from developed countries collect data from developing countries found that Most of these drugs would never be used by the communities from where the experimental data is collected …
  - This is against post trial access …

Main principles in the ethical aspect:

1. **Ethically we should serve patients and our community.**

2. Research Question (RQ): should be relevant to the important health problems present in our country.

3. Researcher must be sure (up to his knowledge) that specific exposure (under study) is not (by any means) harmful to the participants.

4. informed consent ..

you must inform the respondents that:

- **The aim and objectives of the study..**
- **No harm for them up to our knowledge and readings**
- **The possible complications may emerge are …**
- **The choice or refuse of participation is available to them.**

- Get their acceptance through:

Official approvals

Written consent

Verbal or record, or tacit consent

- Fundamental rules for consent:

No rewards

No penalties

The right to withdraw at any time

Anonymity

Confidentiality

5. Decide when to stop & when to proceed:

If we noticed that the agent under study is seems to be harmful … so it is unethical to continue.

at the same time If we noticed that the agent under study is seems to be very beneficial … also it is unethical to continue.

- **Ethical issue in publication:**

Choosing the journal

Follow the policy and style of the journal

Author’s approvals

Corresponding author

Authorship .. Contribution of authors,

Conflict of interests, Funding agency

RESEARCH MISCONDUCT

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- FABRICATION
- FALSIFICATION
- PLAGIARISM … is using other people's work without acknowledging their contribution …. You need permission to use figures and tables from other published sources … (paragraphs??)

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, regulations, and ethics committees can provide guidance but ultimate determinant rests with researcher's value system and moral code